PRECLINICAL AND CLINICAL STUDY OF SIDDHA DRUGS *"RAJAELATHY CHOORANAM"* (INTERNAL) AND "*NATHAI CHOORI ENNAI"* (EXTERNAL) IN THE TREATMENT OF *"KUMBAVAATHAM"* (PERIARTHRITIS)

The dissertation Submitted by

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Dissertation submitted to

THE TAMILNADU DR. MGR MEDICAL UNIVERSITY, CHENNAI-32.

In partial fulfilment of the requirements

For the award of the degree of

DOCTOR OF MEDICINE (SIDDHA)

BRANCH III - SIRAPPU MARUTHUVAM

2014 – 2017

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled Preclinical And Clinical Study Of Siddha Drug "*Rajaelathy Chooranam*" (Internal) and "*Nathai choori Ennai*" (External) in the treatment of "*Kumbavaatham*" (Periarthritis) is a bonafide and genuine research work carried out by me under the guidance of **Dr. N.J. Muthukumar, M.D(S),** Head of the Department**,** Department of **Sirappu Maruthuvam**, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date: **Signature of the Candidate**

Place: Chennai-47 **Dr. C. Shyfa**

ACKNOWLEDGEMENT

- I thank God for giving me this opportunity, providing the strength and energy to fulfil this commitment.
- I express my profound sense of gratitude to **Prof. Dr. V.Banumathi, M.D(S),** Director, National Institute of Siddha, Chennai-47 for granting permission to undertake a study in this dissertation topic and also for providing all the basic facilities in order to carry out this work.
- I extend my sincere heartfelt thanks to **Dr.N.J.Muthukumar, M.D(s)**Head of the Department (i/c)and my Guide, Department of Sirappu Maruthuvam, NIS, Chennai -47, gave his insightful comment at different stages of my research which were thought provoking and they helped me to focus my ideas.
- I express my gratitude and heartfelt thanks to **Dr.R.Raman, M.D(S),** Associate Professor, Dept. Of Sirappu Maruthuvam, National Institute of Siddha, Chennai-47, for his valuable guidance and encouragement.
- I express my grateful thanks to my Lecturer, **Dr.V.Mahalakshmi,M.D(s), Dr.M.V.MahadevanM.D(s)**, **Dr.D.Periyasami,M.D(s)** and **Dr.P.Samundeswari, M.D.(S)** Dept. of Sirappu Maruthuvam, National Institute of Siddha, Chennai-47 for the guidance and encouragement in carrying out this work.
- I am thankful to **Dr. D. Aravind MD(S)** Assistant professor, Dept. Of Botany, National Institute of Siddha, chennai-47 and **Dr.P.Sathiyarajeswaran**, Assistant Director (Scientist 2)-i/c,
- I thank **Dr.A.Muthuvel,M.Sc,Ph.D** (Biochemistry)Associate professor, National Institute of Siddha, Chennai-47 for his guidance in doing chemical studies.
- My special acknowledgements to **Mr.M.Subramanian,M.Sc.,(**Statistics),Senior Research Officer, National Institute of Siddha, Chennai-47, for his valuable help in statistical analysis.
- I thank to **Dr.V.Suba, M.Pharm.,Ph.D,** Associate professor, Dept.of Pharmacology, National Institute of Siddha, Chennai-47 for her interesting teaching of pharmacology and valuable guidance to do this study.
- I thank the library clerk **Mrs.V.Kalpana, Mr.J.Rathinam** library attendant of National Institute of Siddha, Tambaram Sanatorium, Chennai-47, from where I derived much of the literary support.

- I gratefully acknowledge the assistance provided by all other faculties, Well-wisher and staffs of NIS, Chennai who rendered their cooperation throughout the course of study.
- I express my sincere thanks to **Dr.Sivaraman (**Scientist – C) Sathiyabama University for the guidance and encouragement in carrying out this work.
- I wish to dedicate this work to my parents who are helping and sacrificed everything for me and they support in every stage of this work and life.
- I remind thankfully all the animals that lost their lives for the sake of my study and without which i would not have been successful in my study.

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This Certificate is awarded to Dr/Mr/Mrs.....C. Shyja.....

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" RESEARCH METHODOLOGY & BIOSTATISTICS "

FOR AYUSH POST GRADUATES & RESEARCHERS

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 20 th to 24 th July 2015.

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BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Rajaelathy chooranam"** (Internal) and **"Nathaichoori Ennai"** (External) for taken up for Post Graduation Dissertation studies by **Dr.C.Shyfa**, M.D.(S), II year, Department of Sirappu Maruthuvam, 2016, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

Elettaria cardamomum Maton (Zingiberaceae), Fruit
Zingiber officinale Rosc. (Zingiberaceae), Rhizome.
Maranta aurundinacea Linn. (Marantaceae), Rhizome
Taxus baccata Linn. (Taxaceae), Leaf
Piper nigrum Linn. (Piperaceae), Fruit
Syzygium aromaticum (Linn.) Merr. & L.M. Perry (Myrtaceae), Flower bud
Spermacose hispida Linn. (Rubiaceae), Root
Acorus calamus Linn. (Araceae), Rhizome
Allium sativum Linn. (Liliaceae), Bulb
Mesua ferrea Linn. (Clusiaceae) Flower
Ricinus communis Linn. (Euphorbiaceae), Seed oil

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F.No.NIS/6-20/IEC/15-16 Dt: 05.10.2015

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr.C.Shyfa, Department of Sirappu Maruthuvam	
Protocol title: "Preclinical and clinical study of Raja Elathy Chooranam(Internal Medicine) and Naththaichoori Ennai (External Medicine) in the treatment of Kumba Vaatham [Peri Arthritis] with and without Varmam Therapy"	
Documents filed	1) Protocol, 2) Data Collection forms 3) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	Yes
Informed consent documents	Yes
Any other documents	-
Date of IEC approval & its number	NIS/IEC/9/2014-15/15 – 26.08.2015

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

Chairman

Member Secretary

CERTIFICATE

This is certify that the project title. Pre clinical and Clinical Study ~~of~~ Siddha drug 'Rajasalathy Chooranam (EM) and Nathai Choori Ennai (EM) in the treatment of kumbarathram' (Peri arthritis-Shoulder) with and without Varmam therapy. **has been approved by the IAEC.** 100 Rats (50 Male + 50 Female). Approval NO: NIS/IAEC-III/07/29092016.

Prof. Dr. V. Banumathi
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Name of the Principal Investigator – Dr. C. Shyfa.

Name of the Department - Sirappu Maruthuvam.

INTRODUCTION

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ACKNOWLEDGEMENT

INTRODUCTION

Siddha system or indigenous Tamil medicine is a comprehensive system being in practice since time immemorial Tamil land owns a non-detachable tradition of Siddha medical science that has surpassed many attacks and invasions both in land and foreign. The origin of Siddha medical science is attributed to the origin of Tamil language. However historians believed that the period of documented literature falls from 5th century B.C to 14th century A.D. from this period there was systematic development of the Siddha science, our ancients of our country had a clear knowledge about the beneficial effects of medicinal herbs, minerals, and metals arsenic matters upon the various diseases that affect the human body. They learned by wide experience and we have inherited such valuable wealth of palm scripts left by them. When a number of classical works were produced by several authors they were organized as a documented medical Cure system.

A great deal of Siddha medicine comes to us from the selfless work of untiring souls called Siddhars who preferred obscurity .They are the greatest scientists both material and spiritual of ancient period. The Siddhars sought to reveal the deepest truth of human physiology and health. These Siddhars teachings were customarily passed on orally from teacher to student over decades. Siddha is not only a science of medicine but it includes several other disciplines like the *rasavatham* (alchemy*), kayakarpam (rejuvenation), yogam, panjapatchisastram,saram,varmam* etc.

Siddha Medical system enlists 64 kinds of medicine including 32 kinds of internal medicine and 32 kinds of external medicines. They have contributed tremendous work on raw materials from herbal, mineral, and herbo-mineral, metal and animal origin.

The great sage *Yugi* mentioned in his textYugi*vaithyachinthamani* classified vatha diseases into 80 types and *kumbavatham*is one among them that can becorrelated with symptoms of Periarthritis of shoulder joint. . Shoulder pain is the third most common musculoskeletal condition that has alife time prevalence of upto 70% and this seems to be increasing in incidences .prevalence of frozen shoulderis estimated to be 2%to5% in general population. People with diabetic mellitus are at greater risk of developing periarthritis with a prevalence of 10% to12%.Periarthritis shoulder is defined as a clinical syndrome characterized by pain, restriction of both active and passive shoulder movements due to cause within the shoulder joint or remote. The patients have

constant shoulder pain with restriction of movements and unable to do the daily routine activities.

The current clinical treatments mainly include administration of non-steroidal anti-inflammatory drugs, muscle relaxants, physiotherapy, analgesics, and so on. The treatment in other system does not give complete relief. The most optimal treatment has not yet been established. The visitation of *kumbavaatham* increases day by day at Ayothidhas Pandithar hospital and constant shoulder pain and restriction of movement are affecting the routine life, and this reaction made the me to select this treatment protocol.

Hence I had selected "*Rajaelathy chooranam*" (Internal medicine) and *Nathaichoori ennai* (External medicine) along with *varmam theraphy* for treating the disease with minimum cost effective. The selected internal medicine is mentioned in the text *Kosayae Anuboga* Vaithiya *Brahmaragayasam* 2nd part and external medicine in the text *Sarabenthra Vaithiya Muraigal-Vatharoga sigitchai*, the ingredients of internal drug *Milagu- Piper nigrum, Elam - Elattaria cadamomum, Kirambu - Syzygium aromaticum* have the anti-inflamatory, analgesic and anti-oxidant properties.

AIM AND OBJECTIVE

Primary objective

To evaluate the therapeutic efficacy of *Rajaelathy chooranam* (Internal) and *Nathaichoori ennai* (External) along with Varmam theraphy in reducing pain and restriction of movement in the treatment of "*Kumbavatham*."

Secondary objective

- To access the predominance of the disease related to age, sex, occupation etc.
- To correlate the etiology, clinical features, signs and symptoms of *Kumbavaatham* in siddha system with Periarthritis shoulder in Modern science.
- To evaluate the toxicity of trial drug.
- To evaluate the biochemical analysis of trial drug.

SIDDHA ASPECTS

Synonym: *Kumba vali, Paaggu vatham, Paarisa paagu vaatham.*

Definition:

Kumbavaatham *= Kumbam + vaatham*

*(**Kumbam**-* upper part of shoulder, ***Vaatham***- derangement of *vayu thathu)*

Kumba vaatham is a clinical condition characterized by pain in shoulder joint which radiate to arm with restriction of movement.

‘‘நவிலவே தோள்மீதும் கரத்தின் கரத்தின் மீதும்
நலிந்தமெத்த வாகியே நசவுண்டாகும்
கவிலவே கன்னமோடு நயனந்தானும்
கடுத்துமே விறுவிறுப்பு மெரிவுங் காணும்
துவிலவே துடிப்பாகுங் சிரசு தன்னிற்
சுழற்றியே நாபிக்கீழ் வலியுண்டாம்
அவிலவே அடிநாக்கில் அழன்று காணும்
மலருமே வருகும்ப வாதந்தானே’’.

-Yogivaithiya chinthamani

- Clinical Pain in shoulder and arm.
- Muscle weakness in shoulder and arm
- Burning sensation in eyes and cheeks.
- Giddiness and twitching over the scalp
- Pain below the umbilicus.
- Burning sensation in the tongue

PAAGU VAATHAM

‘‘தூயோர் பாகுவாதம் இருதோளில் கடுப்பாம்
ஆயோ வென்று அரற்றுபகல் அல்லும்.’’

- *Agathiyar vaithiya chinthamanivenbaa-4000*

Pain present in both shoulder joint causing sleep disturbances

PAARISA PAAGU VAATHAM:

‘‘தூங்காமல் நோய் செய்யுத் தோளொன்றி வாதமிகு
பாங்காகும் பாரீசபாகு’’

- Agathiyar vaithiya chinthamanivenbaa-4000

Pain in any one of the shoulder joint with sleep disturbance

The symptoms of ***Paagu vaatham*** and ***Paarisapaagu vaatham*** can be compared with *Kumbavatham.*

AETIOLOGY:

According to text *Yugi vaidhya chinthamani*

- Lying in cold floor leads to *Kumbavaatham*

According to the text '*Pararasasekaram'*

- Intake of acrid, bitter, pungent containing foods
- Excess intake of grains
- Irregular sleeping pattern
- Excessive food conception, frequent starvation
- Sexual indulgence
- Increased fear, anger, and sadness
- Over exposure to air.
- Irregular diet timings will produce Vaatha diseases.

According to the text *Sarabenthirar Vaithiya Muraigal- Vaatha Rokha Sikitchai*

- Consuming low quantity of food.
- Sexual indulgence
- Reduced sleep
- Doing heavy work
- Weakness due to sorrow, diseases, worries
- Control of reflexes like defecation and urination
- Conversion of undigested food into toxic substances (Aamam)
- Trauma
- Control of hunger
- Injuries in Uyirnilaigal
- Falling down from vehicle
- Doing heavy works

Classification of *Vaatham:*

Various siddha texts give different classification of the *Vaatha* disease as follows

SL. NO	NAME OF SIDDHA TEXT	TYPES
1.	*Agasthiyar* – 2000 “எண்பது வாதமாகு மருவகைப்படுத்திக் காணின் நண்புறு அரைக்குமேலே நாற்பது வாதமாகும் பணிச்சேரைக்குக் கீழே பத்து நான்காகுமென்று வண்டுசேர் குழலினாளே வாதத்தின் கூறுதானே”	80
2.	*Agasthiyar Gurunaadi*– 235	84
3.	*Agasthiyar Rathina Churukkam* – 500 “மாற்றமே வாதரோகம் வகை எண்பத்து நாலே”	84
4.	*Ashataanga Sangiragam*	85
5.	*Bohr Vaidhiyam* – 700 “வாச்சென்ற வாதம் எண்பதுவும் போகும்”	80
6.	*Jeeva Rakshaamirdham*	80
7.	*Noi naadal and Noi Mudhal Naadal* – Part II	85
8.	*Thanvandhiri Vaidhiyam*	80
9.	*Theraiyar Vaagadam*	81
10.	*Yogi Vaidhiya sindhaamani perunool* – 800 “என்னவே வாதமது என்பதாகும்”	80
11.	*Yogai Vaidhiya sindhaamani perunool* – 800	84

	“ஆமப்பா வாதம் மெண்பத்து நாலு அதனுடைய குணா குணங்க லடங்கலாக”	
12.	*Rathina surukka naadi* **“**நாளடா நாற்பத்து நாலு நூறு நயமுடனே நாற்பத்து எட்டு ரோகம் பாரப்பா வாதமது”	84

Locations of V*aatham:*

Below the navel

“நாமென்ற வாதத்துக் கிருப்பிடமே கேளாய்
நாபிக்குக் கீழென்று நவில லாகும்”

- யூகிமுனி

As per *Yugi muni, Vaatham* lies in

1. Abaanan
2. Edakali
3. Kamakodi
4. Undhiyin keezh
5. Hip region
6. Bone
7. Muscles
8. Nerve
9. Joints
10. Skin
11. Hair follicles and
12. Stools

Vaatham in normal state lives in Gastro Intestinal Tract, Bones, Ear, Thigh, Hip and Skin.

Qualities of *Vaatham:*

1. Kadinam	-	Roughness
2. Varatchi	-	Dryness
3. Elesu	-	Light
4. Kulirchi	-	Coldness
5. Asaithal	-	Unstableness
6. Anuthuvam	-	Subtleness

Opposite Qualities

1. Miruthu	-	Softness
2. Pasumai	-	Unctuous
3. Paluvu	-	Heaviness
4. Akkini	-	Hotness
5. Sthiram	-	Stableness
6. Katti	-	Solidity

Types of V*aatham*

The Siddha classical texts divide the general principles of Vatham into ten subsidiary forms that differ from one another by their location in the body (Anatomical) and by their particular functions (Physiological).

They are:

1. ***PRAANAN*: (Heart Centre)**

   It regulates the respiration and digestion. It is otherwise called as "Uyirkkaal"

2. ***ABAANAN*: (Moolaadharam Centre)**

   It moves in the whole Genito - Urinary tract and regulates the defaecation, Micturation, menstruation, parturition, ejaculation. It is otherwise termed as 'kezhnokkukaal'

3. ***VIYAANAN* (Fore head Centre)**

   It helps in the circulation of energy throughout the entire nervous system and the movements of various parts of the body. It is also transports nutrients and blood throughout the entire body. It is also known as 'Paravukaal'.

4. ***UDHAANAN*: (Throat Centre)**

   This corresponds to the pharyngeal plexus in the throat region and controls speech and breathing. It is also responsible for the physiological reflex actions like vomiting, hiccup, cough, etc., It is otherwise named as 'Melonokkukaal'

5. ***SAMAANAN*: (Navel Centre)**

   This corresponds to the navel region and control digestion. It balances the other 'Vayus. It is also called "Nadukkaal".

6. ***NAAGAN*: (Intellectual air)**

   It is responsible for the intelligence of an individual, winking, singing, and pilo erection.

7. ***KOORMAN:* (Visual)**

   It is responsible for yawing, closing of mouth (immovable of lower jaw) winking, shedding, of tears, /vision and opening of the eyes.

8. ***KIRUGARAN*: (Secretory air)**

   It is responsible for salivation and nasal secretion. It helps in digestion and meditation. It produces Cough and sneeze.

9. *DEVADATHTHAN*: (Tiresome air)

Laziness is attributed to Devadaththan. Ocular movements & human passions are attributed to this Vaatham. It stays either at the anus or at urinary orifice.

***10. DHANAJAYAN*: (INTRACRANIAL AIR)**

Dhanajayan functions from the nose & it is responsible for the bloating of the body after death and also for the foul smell.

THATHU'S AND THEIR FUNCTIONS:

Vatham	-	Separation/ Movement
Pitham	-	Conversion/ Transformation
Kabam	-	Cohesion/Liquidity

These three humours Vaatham, Pitham and Kabam circulate in the body in different proportions and help in the digestion of food and other general physiological functions. The right proportion of each, in proper combination is responsible for maintaining the good health.

When some of the factors like diet, occupation, seasonal variation etc., disturb Vaatham, it loses its control, which may be diminished or exaggerated. So the two Uyir thathus are also disturbed which leads to the genesis of "Vaatha" diseases. Now the Uyir thathu Vaatham can be termed as "Vaatha thodam"

DERANGEMENT OF VAATHAM:

1. Body ache
2. Pricking Pain
3. Tearing Pain
4. Nerve weakness
5. Mental distress
6. Movements
7. Joints pain
8. Traumatic pain
9. Dislocation of joints
10. Weakness of organs
11. Paralysis of limbs
12. Polydypsia
13. Sever pain in calf and thigh muscles

14. Bony pricking pain
15. Anurea and constipation
16. Unable to do flexion and extension of the limbs
17. All tastes to be like astringent
18. Excess Salivation

SIDDHA PATHOLOGY:

When some of the factors like diet, occupation, seasonal variation etc., disturb Vaatham, it loses its control, which may be diminished or exaggerated. So the other two Uyir thathus are also disturbed which leads to the genesis of "Vaatha" diseases. Now the Uyir thathu Vaatham can be termed as "Vaatha thodam, this simultaneously leads to derangement of Udal thaathukkal which produces the symptoms of disease.

STATUS OF VATHAM AS PER SEASONS:

As per season, the three Uyir thathus gets altered Physiologically Vaatham will be pronounced in the last phase of Muthuvenil (Thannilai valarchi), Karkalam (Vetrunilai valarchi) & First phase of Koothir Kalam (Thannilai adaithal)

[Ref: Siddha maruthuvanga Churukkam]

FACTORS WHICH ALTER VATHAM:

"வாயுவின் குணத்துடன் சூடனுலகில்
வாயுவினி டங்களில் நோய்களுண்டு
வாயுவில் குளர்ச்சிதான் கூடிடலோ
வந்திடும் நலிகளும் வேறிடத்தே
வாயுவில் அனல்தரும் நெய்ப்பமைந்தால்
வாயுவும் அடங்கிடும் வாய்மையிது
வாயுவின் பிணிகளைப் போக்கிடவே
வகுத்திடும் முனிமொழி கண்டிடுமே"

- சித்த மருந்துவாங்க சுருககம்

1. When hot foods are taken in a vitiated status of Vaatham, “Vaatham” gets Thannilai valarchi.
2. When cold foods are taken in a vitiated status of Vaatham, “Vaatham” gets Vetrunilai valarchi.
3. And when only oil foods with hot foods are taken in a vitiated status of Vaatham, “Vaatham” attains “Thannilai (neutralizes) i.e. in its own state that means healthy conditions.

THE FEATURES OF EXAGGERATION OF VAATHAM:

1. Body weakness and darkness
2. Liking to eat hot foods
3. Shivering
4. Abdominal distension
5. Constipation
6. Diminution of immunity
7. Giddiness
8. Insomnia
9. Laziness

THE FEATURES OF DIMINUTION OF VAATHAM:

1. Body ache
2. Hoarseness of voice
3. Loss of memory
4. Semi consciousness
5. Difficulty to do any work
6. Paleness and coolness of body
7. Heaviness of body
8. Cough, sleep and abdominal distention

[Ref: Siddha Maruthuvanga Churukkam]

Symptoms of deranged Vaatham:

The signs and symptoms of Vaatha disease have been given in many siddha classical text books as follows

1. In Agasthiyar – 2000

''வாதத்தின் குணமேதென்னில மயக்குந்தியெங்கும் மலர்சிவக்கும்
பாதங்குளிர்ந்து சருவாங்கம்பற்றி நடக்குமுகங் கடுக்குஞ்
சீதத்துடனே வயிறுபுண்ணாஞ் சிரிப்பித் ததுந்தெறி – மூச்சாம்
போதத் தண்ணீர்தான் வாங்கும் புகழும் பஞ்ச குணமாகுமே''

1. Unconsciousness
2. Tingling pain in the face
3. Redness of eyes
4. Dysentery
5. Excessive thirst
6. General body pain
7. Chillness of feet

2. Agasthiyar Naadi:

''சொல்லவே வாத மது மீறிற்றால்
சோர்வடைந்த வாயுவினால் தேகமெங்கும்
மேல்ல கைகால் அசதி யுண்டாகும்
மேயமுடங்கும் நிமிரவொண்ணாத் திமிர் உண்டாகும்''

- அகத்தியர் நாடி

3. Theraiyar Vaagadam:

''வாதவீறு அன்னமிறங்காது கடுப்புண்டாகும் வண்ணமுண்டாம்
மோது கட்டுரோகம் சுரமுண்டோ மிருமலுமா முறங்காதென்னும்
ஒதுசூரிய வாதமனலாகு நடுக்கமுண்டாம் பொருள்களாய்த்
தீதெனவே நரம்பிசித்து சந்துகள்தோறும் கிடுக்குந்தானே''

- தேரையர் வாகடம்

1. Loss of appetite
2. Tingling sensation
3. Fever
4. Cough
5. Sleeplessness
6. Tremor and
7. Pain in all the joints

NOI KANIPPU VIVADHAM (DIFFERENTIAL DIAGNOSIS)

Some types of Vaatha diseases may mimic like Kumbavaatham. Careful and clear history taking and examination will reveal the correct diagnosis.

தோள் வாதம்

"தோளதிலே வீக்கம் கண்டு
துடர்ந்திடும் பிடரி கண்ணும்
நாளது மூன்றின் மேலே
நல்லதோர் கடுப்பும் காட்டும்
ஆனது சகித்திடாது பாரில்
அடுத்திடும் தோளில் வாதம்
சுளிது சிரத்துள் நீர் தானும்
சூழ்ந்திழல் அணுகும் தானே"

Clinical features of

- Swelling in shoulder region.
- After three days unbearable pain sensation in occipital region and eyes.
- Fluid accumulates in head.

சகனவாதம்

"கேளுமே கழுத்தின் கீழ் அரைக்குமேலும்
கேடியான கரம் இரண்டும் மிகவேநெந்து
வாளுமே சரீரமெல்லாம் கனத்திருக்கும்
வாலிபருக்கு மனம் கண்ணு மயக்கமாகும்
ஏளுமே இரண்டு கண்ணும் எரிச்சல் உண்டாம்
ஏற்றமாய் மலந்தாறும் இறுகிக் காணும்
கோளுமே கொட்டினது போல் கடுக்கும்
சகன வளிநோயினூட தீர்க்ந்தானே"

CEGENAVAATHAM

- Pain in the upper back, which is identical with the cervical spine
- Radiating pain in both the upper limbs
- Feeling of heaviness of the body
- Mental depression
- Giddiness
- Burning sensation in the eyes
- Constipation.

வுளிக்கீல்வாயு

வலிக்குத்தல் வீக்கங் காணும்
வாய்தொண்டை வறட்சிகாய்ச்சல்
தலைவலி மார்து டிப்புத்
தாங்கொணா வலிவீக் கந்தான்
நிலவுகாற் கணுக்கு றங்கு
நீடுதோள் முழங்கைக் காற்காம்
மலக்குடற் கட்டு வேர்வை
வாதத்தில் வாய்வி தாமே.

VALI KEEL VAYU

- Pricking pain and swelling of joints
- Dryness of mouth and throat
- Fever
- Headache
- Palpation in chest.
- Intolerable pain of the major joints like knee

PATHIYAM:

The tastes which increase "Vaatham" are Sour and Astringent.

"புளிதுவா விஞ்கங்கறி யாற்பூரி கும்வாதமே
ஒளியுவர் கைப்பேறில் பித்துசீறும் - கிளிமொழியே
கார்ப்பினிப்பு விஞ்களஞ் சட்டிரதச்
சேரப் புணர் நோயணுகாதே"

The tastes which neutralize Vaatham are Sweet, sour and salt.

"வாத மேலிட்டால் மதுரம் புளியப்பு
சேதமுறச் செய்யுஞ் சிறையும் - ஒதக்கேள்
காரந் துவர் கசப்பு காட்டுஞ் சுவையெல்லாம்
சாரப் பரிகாரஞ் சாற்று"

- Kannusamiam

LINE OF TREATMENT

Universe and body were made up of five *Boothams*. Any irregularity in them causes diseases. In Siddha system of Medicine, the line of treatment plays an important role in the normalization of *Pancha boothams*. In Siddha system, the treatment is based on *mukkutram* theory.

Treatment is not only for curing the disease but also for the prevention recurrence of the symptoms and rejuvenation of *udal kattugal.*

The main goal of the treatment was not only healing the disease but also the prevention of disease and rejuvenation of *udalkattugal.*

These were as follows:

1) Neekkam (Treatment)
2) Niraivu (Restoration)
3) Kaappu (Prevention)

Neekkam (Treatment)

The deranged Vaatham can be balanced by purgation. Hence the purgation drug meganatha mathirai 2 at early morning with warm water was given a day before treatment then the Internal and external drugs were given.

Internal drug:

Raja elathy chooranam- 1gm twice a day with warm water

External drug:

Nathaichoori Ennai– was given for external application over the affected area.

External therapy – Varmam therapy

Niraivu (Restoration)

The diet should be normalizes the Vaatham and also strengthen the body.

Dietary Regimens:

According to 'Siddha Maruthuvanga Churukkam'

செங்கழு நீர்கோஷ்டந் தேன்மிளகு நல்லெண்ணெய்
தங்குபெருங் காயந் தழுதாழை- எங்கெங்கும்
கூட்டுசிறு முத்துநெய் கோதில் உழுந்திவைகள்
வாட்டுமனி லத்தை மதி

1. Senkazhuneer
2. Costus root
3. Honey
4. Pepper
5. Gingely oil
6. Asafoetida
7. Thazhuthaazaai
8. Castor oil
9. Black gram

These were the food items for the Vaatha patients.

Add:

Tender vegetables:

- Avarai (*Dolichos lablab*)
- Aththi (*Ficus racemosus*)
- Murunkai (*Moringa oleifera*)
- Sundai (*Solanum torvum*)
- Mullangi (*Raphanus sativus*)
- Thoothuvelai (*Solanum trilobatum*)
- Pirandai (*Cissus quadrangularis*)
- Karunai kizhangu (*Colocasia antiquarum*)
- Kathiri (*Solanum melongena*)

Greeens:

- Sirukeerai (*Amaranthus tricolor*)
- Mookkurattai (*Boerrhavia diffusa*)
- Puliyaarai (*Hibiscus cannabinus*)
- Ponnankanni (*Alternanthera sessili)*
- Manali (*Gisekia pharanaceoides*)
- Mudakkaruththaan (*Cardiospermum halicacabum*)

Pulses:

- Ulunthu (*Vigna mungo*)
- Pottukkadalai (fried *Cajanus cajan*)

Dairy products:

- Cow's milk, buttermilk

AVOID:

- Tubers except karunai kizhangu (*Colocasia antiquorum*)
- Maaporulghal (Carbohydrates)
- Vaazhai (*Musa paradisiaca*)
- Kaaramani (*Vigna unguiculata*)
- Verkkadalai (*Arachis hypogea*)
- Pattaani (*Pisum sativum*)
- Mochai (*Lablab purpureus*)
- Kezhvaragu (*Eleusine coracana*)
- Kambu (*Pennisetum typhoideum*)
- Solum (*Sorghum vulgare*)
- Sour, astringent foods

Kaappu (Prevention)

The prevention of diseases were well said in the Siddha system of Medicine as mentioned in the text '**Theraiyar Pinianugaa Vithi'**

பாலுண்போம் எண்ணெய்பெறின் வெந்நீர் குளிப்போம்
பகற்புணரோம்; பகற்றுயில்வோம்: பாயோதரமு மூத்த
ஏலஞ்சேர் குழலியரோ டிளவெயிலும் விரும்போம்;
- ரண்டடக்கோம்; ஒன்ரைவிடோம்; - டதுகையிற் படுப்போம்.

Varmam

Varmam is an art as well as a science. As an art it can be employed to attack a person to disable him and as a science it helps persons recoup from impact of such attacks. *Varmam* has also some similarities to other martial arts such as Silambam, sword fighting, Kalari etc.

The study of Varmam helps us to know the secrets of nerve centres and the disease caused and the appropriate treatment prescribed.

Hundreds of nerve-centres of the human body lie dormant with bones, nerves, veins, muscles, joints and inner organs and are found either deep or at the surfaces of the body. Vital life centres are dominant on bones and joints; medium life centres on nerves; striking life centre on veins. Inner life centres on muscles, and chronic life centres on blood clots formed due to impacts on the body.

Varmam can be defined as the flow of life force in relationship with breathing.

"செப்புறு தசைகளென்பு சிறு பெரு நரம்புசந்து
தப்புறு நாடியாறும் தங்குமிடம் வன்மமாமே."

- Varma Vidhi

The points where life force resides and flows in the human body are known as varmam. It also means the points where breathing energy resides in the body.

"வாசி தட்டும் தலமெல்லாம் வர்மம்."

- Varma Odivu Murivu Sara Soothiram-1200

Varmam therapy is a systematic study of vital points (Varmam) on human body and also on animal bodies.

"உள்ளபடி நூற்றெட்டு தலம் சாவாகும்
உணர்வாகி அத்தலங்கள் உயிரு மாகும்
கள்ளமுற்ற அத்தலங்கள் பிணியு மாகும்
களங்கமற்றால் அத்தலங்கள் சுகமே காணும்
உள்ளுணர்வாய் அத்தலங்கள் வாசி யேற்ற
உற்றதினால் அத்தலங்கள் உறுதி சேரும்
புள்ளடிபோல் அத்தலங்கள் கண்ட வர்கள்
புகலார்கள் எல்லோரும் புவியினுள் ளோர்க்கே."

-Varma Odivu Murivu Sara Soothiram-1200

It is also called the art of killing and the art of healing. Right or wrong vibration of the vital points will either promote or impair health. Its aim is to produce healthy and stable individuals.

Classification of Varmam:

There are 108 Varmam or Varma points in our body.

1. **According to the text Varma Odivu Murivu Soothiram,**

1. Padu Varmam - 12
2. Thodu Varmam - 96

Injury or any hit in the Paduvarmam points may lead to severe deformities or even death. The Thodu Varmam points are mostly used in therapeutic purposes.

2. According to the text Varma Kannaadi

Human body is divided into five divisions, they are:

S.No	Area	Number of points
1	From top of the head to neck	25
2	From neck to navel point	45
3	From navel point to anus	9
4	Both hands	14
5	Both legs	15
Total		108

4. **According to the text Varma Soothiram,**

Vaatha Varmam	-	64
Pitha Varmam	-	24
Kaba varmam	-	06
Ull Varmam	-	06
Thattu Varmam	-	08
Total	-	108

The main causes for impact to nerve centre (Varmam)

“கேளப்பா தடியடிகள் படுத லாலும்
கெடியான எறிவிசைகள் கொள்ள லாலும்
வாளப்பா கட்டைகுற்றி தட்ட லாலும்
மாற்றானின் கைப்பிடிகள் படுதலாலும்
வேளப்பா ஆகசா மதிலே நின்று
மெய்மறந்து கைமறந்து விழுத லாலும்
தாளப்பா பற்பலவாம் விதத்தி னாலே
சங்கையில்லாக் காலமது சாருந் தானே.

-Odivu Murivu Saari-1200

- Hit sustained by a thick and rough stick.
- Stone thrown at a high speed from a sling.
- Fall from a tree or height.
- Fall while running.
- By leaping.
- By fainting

Varma Kalai is said to link up the material body with the spiritual ‘life’ or Soul, through the mediums of panchabhootham activating the movement of “life” within the body carried through the ten vayus. This is the fundamental principle of Yogam and Samadhi.

A human body requires thasavaayus (10 vaayus) namely, Praanan, Abaanan, Udaanan,Viyaanan, Samaanan, Naagan, Koorman, Kirukaran, Devadatthan and Dananjayan,for its proper functioning each Vaayu has its own function to keep the body healthy and disease free.

BHUJA VARMAM

Synonyms

Poruthu varmam

Kaiporuthu varmam

Kaipuja poruthu varmam

Cheppu varmam

புஜ வர்மம்

ஆகுமே புஜவர்ம தலத்தைக் கேளு
ஆனகைப் பொருத்தின் தலம தாகும்
போகுமே இத்தலத்தில் காயங் கொண்டால்
பொருத்துவிட்டு எல்லுதான் விலகிப் போகும்
வேகுமே கையதனை உயர வொட்டாது
வீக்கமாம் தேகமெல்லாம் வியர்த்து தளரும்

Location

Bhuja varmam rests at the tip of the collar bones on either side. Each upper arm has a Bhuja varmam.

Features

- The victim of this disorder will not be able to lift the hands freely.
- The areas will become numb and swelling will set in.
- The patient will not have a wink of sleep and become faint.
- Sleep will be disturbed.

Method of treatment:

Bring the patient back to consciousness. Give massage on the opposite side of the affected life centre. Also rub the back and side ribs.

Benefits

Used in the disease of shoulder joint and other Vaatha diseases

KAVALI VARMAM

Synonyms

Kavali kaalam

kavali adangal

channi adangal varmam.

“போடவே தீர்ந்துவிடும் இன்னு மொன்று
புகழான கவளிதனில் கவளி வர்மம்
நாடவே இத்தலத்தில் முறிந்து போனால்
நாழிகைதான் தொண்ணூறில் மரண மாவார்
தேடவே இது கடந்தால் தொண்ணூறாம் நாள்
திண்ணமாய் மரித்திடுவான் இயல்ப தாக”

Location:

Kavali varmam is located in the webs between the fingers on both hands. In appearance this place looks like the letter ‘v’. This formation is known as Kavali. The Kavali varmam resides in the depressions between the fingers.

Benefits

It is used in the treatment of diseases in upper limb.

ULLANKAIVELLAI VARMAM

Synonyms:

Vellai Varmam	- Varma Kannadi-500
Adi kuzhi	- Varma Vidhi
Munnoli Varmam	- Varma Soothiram Panjikarana Pinnal
Karunasakkira kaalam	- Varma Aani
Kunju pichathi kaalam	- Varma Vilakkam

Location:

"கீர்த்தியாம் பாதமதில் வெள்ளை வர்மம்."

- Varma Odivu Murivu Sara Soothiram -1200

"சூட்சமடா வெள்ளையதில் அடங்கல் வர்மம்."

- Varma Soothiram- 101

"படைமுறித்தான் வர்மத்துக்கு இரண்டு விரலுக்குக் கீழே உள்ளங்கால் வர்மம் **.....**

-Varma Noolalavu Nool

"அவனிதனில் உள்ளங்கால் வெள்ளை வர்மம்."

- Varma Peerangi-100

"அகமான உள்ளம் கால் வெள்ளை வர்மம்."

- Adi Varma Sootcham-500

In the centre of the plantar region

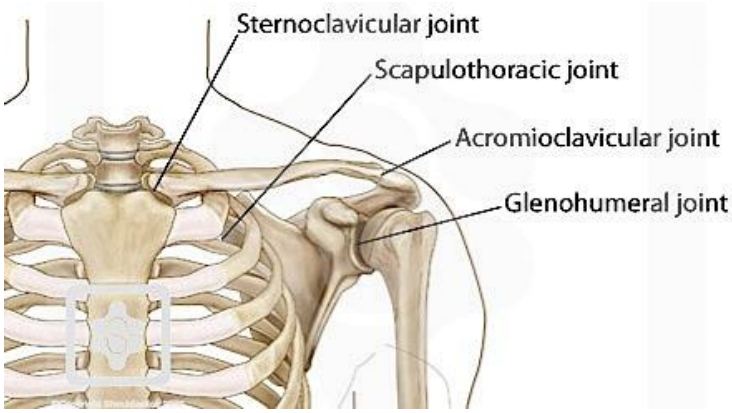
Benefits

It cures the diseases in palm, hyperhidrosis in palms and the Vaatha diseases affecting the joints.

MORDEN ASPECT

ANATOMY OF SHOULDER JOINT:

The shoulder joint is the proximal joint of the upper extremity and is the most mobile of all joints in the human body. The shoulder is the region of upper limb attached to the trunk. The bone frame work of the shoulder consists of the clavicle, scapula and proximal end of humerus.



JOINTS OF SHOULDER JOINT:

There are three joints in the shoulder complex namely

Glenohumeral joint

Sternoclavicular joint

Acromio clavicular joint

Glenohumeral joint:

The main joint is the glenohumeral joint. It is a multiaxial ball and socket joint and it is the most mobile joint in the body. The head of the humerus is called the ball and the glenoid fossa of the scapula is called the socket. The glenoid cavity depth is increased by a rim of fibrocartilage that surrounds it. The rim of fibrocartilage is the glenoid labrum. Superiorly this larum is continuous with the tendon of long head of biceps brachii muscle, which attaches to the supraglenoid tubercle and passes through the articular cavity superior to the head of the humerus. The synovial membrane attaches to the margins of articular surfaces and lines the fiberous membrane of joint capsule. Synovial membrane is loose inferiorly. This redundant region of synovial membrane and related fibrous membrane accommodates abduction of the arm.

The joint stability is provided by rotator cuff muscles, the long head of biceps brachii muscle, related bony processes, and extracapsular ligament.

Sternoclavicular joint:

The sternoclavicular joint is a sole connection between the axial skeleton and upper extremity. It connects the inner part of the clavicle to the sternum. It allows 30-60 of upward elevation, 35 of anteroposterior movement and 45-50 of rotation about the long axis of the clavicle.

Acromioclavicular joint:

This joint connects the outer part of clavicle to a projection at the top of the shoulder blade called the acromion process. It is the only articulation between clavicle and scapula little motion exists in this joint. This joint is an encapsulated diarthrodial joint held together by its joint capsule and coracoacromial ligaments (trapezoid and conoid ligaments)

Rotator cuff:

The supra spinatus, infraspinatus, teres minor and subscapularis muscle comprise the rotator cuff. The muscles and tendons of the rotator cuff form a sleeve around the anterior superior and posterior humeral head and glenoid cavity of the shoulder compressing the glenohumeral joint.

MUSCLES OF SHOULDER JOINT

The most superficial muscles of shoulder are trapezius and deltoid together they provide characteristic contour of the shoulder

Deep to the trapezius the scapula is attached with vertebral column by three muscles- the levatorscapulae, rhomboid minor and rhomboid major.

1. DELTOID:

It is large and triangular in shape, with its base attached with the scapula and clavicle and its apex attached with humerus.

Origin

Inferior edge of the crest of spine of the scapula, lateral margin of the acromian, anterior border of lateral one- third of the clavicle.

Insertion

Deltoid tuberosity of humerus.

Innervation

Axillary nerves (c_5,c_6)

Functions

- abductor of the arm
- Clavicular fibres assist in flexing the arm
- Posterior fibres assist in Major extension of the arm

2. TRAPEZIUS

The muscle has an extensive origin from the axial skeleton. Together the left and the right trapezius muscle form a diamond or tapezoid shape.

Origin

Superior nuchal line, external occipital protruberance, medial margin of ligamentum nuchae, spinous process of C_7 to T_{12} and related supraspinous ligaments.

Insertion

Superior edge of the crust of the spine of the scapula, acromian, posterior border or 0f lateral one-third 0f the clavicle.

Innervation

Motor spinal part of accessory nerve

Anterior rami of C_3 and C_4

Functions

- Powerful elevation of scapula.
- Rotates the scapula during abduction of humerus above horizontal.
- Middle fibers retracts scapula.
- Lower fibers depresses scapula.

3. LEVATOR SCAPULAE

It elevates the scapula

Origin

Transverse processes of C_1 and C_2 vertebrae and posterior tubercles of transverse processes of $C_3$and C_5 vertibrae.

Insertion

Posterior surface of medial border of scapula from superior angle to root of spine of scapula.

Innervation

Branches directly from anterior rami of C_3 and C_4 spinal nerves and by branches (C_5) from the dorsal scapular nerve.

Function

Elevates the scapula.

4. RHOMBOID MINOR

Origin

Posterior surface of ligamentum nuchae and spinous process of C_7 and T_1 vertibrae.

Insertion

Posterior surface of medial border of scapula at the root of spine of scapula.

Innervation

Dorsal scapular nerve ($C_{4,}$ C_5)

Function

Elevates and retracts the scapula.

5. RHOMBOID MAJOR

Origin

Spinous processes of T_2-T_5 vertibrae and innervating supraspinous ligaments.

Insertion

Posterior surface of medial border of scapula from the root of the spine of scapula to the inferior angle

Innervation

Dorsal scapular nerve (C_4, C_5)

Function

Elevates and retracts the scapula.

SUPRASPINATUS:

Origin:

Medial two - thirds of the supraspinous fossa of the scapula and the deep facia that covers the muscle.

Insertion:

Most superior facet on the greater tubercle of the humerus

Innervation:

Suprascapular nerve (C5,C6)

Function:

Rotator cuff muscle; initiation of abduction of arm to 15^0 at glenohumeral joint.

INFRASPINATUS:

Origin :

Medial two thirds of infraspinous fossa of the scapula and the deep facia that **covers the Insertion:**

Middle facet on posterior surface of the greater tubercle of the humerus.

Innervations:

Suprascapular nerve (C5,C6)

Funtion:

Rotator cuff muscle; lateral rotation of the arm at the glenohumeral joint

TERES MINOR:

Origin:

Upper two thirds of a flattened strip of bone on the posterior surface of the scapula immediately adjacent to the lateral border of the scapula.

Insertion:

Inferior facet on the posterior surface of the greater tubercle of the humerus.

Innervations:

Axillary nerve (C5,C6)

Function :

Rotator cuff muscle; lateral rotation of arm at the glenohumeral joint.

TERES MAJOR:

Origin:

Elongate oval area on the posterior surface of the inferior angle of the scapula.

Insertion:

Medial lip of the intertubercular sulcus on the anterior surface of the humerus.

Innervation:

Infrior subscapular nerve (C5, C6, C7)

Function:

Medial rotation and extention of the arm at the glenohumeral joint.

LONG HEAD OF TRICEPS BRACHII:

Origin;

Infraglenoid tubercle on scapula

Insertion:

Common tendon of insertion with medial and lateralheads on the olecranon process of ulna

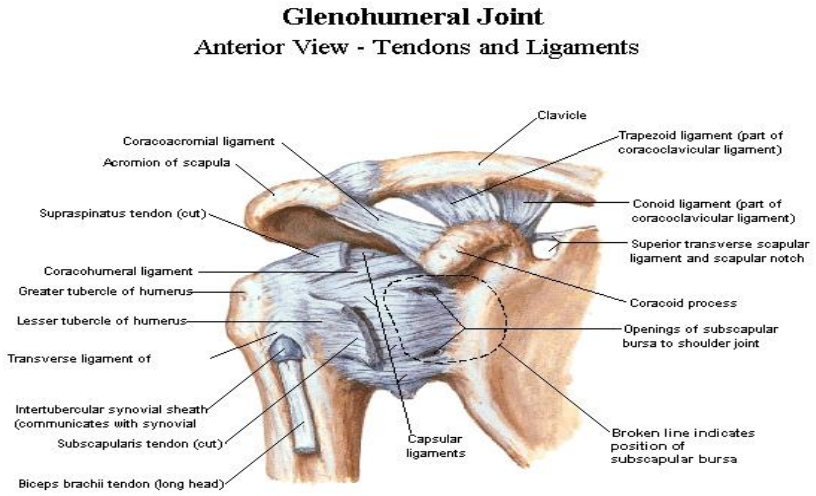
Innervations:

Radial nerve (C6, C7, C8)

Function:

Extension of the forearm at the elbow joint; accessory adductor and extensor of the arm at the glenohumeral joint.

LIGAMENTS OF SHOULDER JOINT



Ligaments of the Acromioclavicular joint:

- Capsular ligament
- Superior and inferior acromioclavicular ligament
- Articular disc
- Coracoclavicular ligament (trapezoid and conoid ligament)

Ligaments of sternoclavicular joints

- Capsular ligament
- Anterior and posterior sternoclavicular ligament
- Inter and costoclavicular ligament
- Articular disc

Ligaments of glenohumeral joint

- Capsular ligament
- Coraco humeral ligament
- Glenohumeral ligament
- Transverse humeral ligament
- Glenoid of humerus

BURSAE:

Shoulder bursae refers to sacs surrounding the shoulder joint that are filled with synovial fluids. As with bursae in general, they facilitate movement and reduces friction at tendon-tendon and tendon-bone interfaces.

VASCULAR SUPPLY:

Acromioclavicular joint:

It receives its arterial supply from the suprascapular and thoracoacromial arteries.

Sternoclavicular joint

It receives blood supply from inter thoracic and suprascapular arteries.

Glenohumeral joint

Supplied by branches from anterior and posterior circumflex humeral suprascapular and circumflex scapular vessels.

DYNAMIC PHYSIOLOGY OF SHOULDER JOINT

Joints within the shoulder joint allow movements in three planes in space and also motion in combination of three planes.

- Flexion and extension in sagittal plane.
- Abduction and adduction in the frontal plane.
- Flexion and extension in horizontal plane while the arm is abducted to 90°
- Axial rotation, which is the result of movements performed relatively to any two of three axes
- Circumduction which combines movements of all the three axes, its amplitude being defined as the code of circumduction.

Range of motion

Movements of flexion and extension performed in the sagittal plane normally range from 180° of flexion to 45° from 30° of adduction to 180° of abduction.

Motions of upper limb in horizontal plane take place about a vertical axis and range from an angle of 30° posterior to the vertical plane of the body to an angle of 140° anterior to this plane. The axial rotation of the arm normally measures from 80° of external rotation to 90° of internal rotation. Movements that may be required of the shoulder in activities of daily living are complex.

PERIARTHRITIS SHOULDER

E. Cod man coined the term “Frozen shoulder” in 1934 and described it as a condition difficult to define, difficult to treat and difficult to explain from the point of pathology.

Earlier S Duplay used the term “Periarthritis Scapulo – humerale” to describe the condition in 1872.

Later J Neviaser used the term “Adhesive capsulitis” in 1945 reflecting the findings at surgery and postmortem.

Definition

It is defined as a clinical syndrome characterized by painful restriction of both active and passive shoulder movements due to causes within the shoulder joint or remote (other parts of the body) It is usually unilateral. Both shoulders may be affected in about 10 to20% of cases (mainly Diabetic mellitus)

Epidemiology

Frozen shoulder syndrome usually affects patient aged 40-60 years. The incidence is not precisely known however it is estimated that 2%to 5% of general population develops the disease over their life time. Men tend to be affected less frequently than women, and there is no predilection for race .In general bilateral shoulder involvement is rarely simultaneous and instead occurs sequentially.

Pathophysiology

Immune, inflammatory and fibrotic changes appear to be involved in the pathophysiology of frozen shoulder. The current hypothesis posits inflammation in the joint capsule followed by development of adhesions and fibrosis of the synovial lining. Thickening and contraction of the glenohumeral joint capsule and formation of collagenous tissue surrounding the joint reduces joint volume.

Matrix metalloproteinase are involved in the constriction of extra cellular matrix and in various cytokines that control collagen deposition. The drugs that inhibit matrix metalloprotiens can induce conditions similar to frozen shoulder and duputryen disease

Following the synovial inflammatory process, a high number of fibroblast and myofibroblast suggest a fibrotic process in the capsule. The condition is thought to result from progressive fibrosis and eventual contracture of the capsule of the gleno humeral joint, which causes pain and stiffness.

CAUSES

Primary: Here the exact cause is not known and it could be idiopathic.

Secondary: according to Lumberg, the secondary causes are

- Shoulder causes
- non-shoulder causes

Shoulder causes: problems directly related to shoulder joint which can gives rise to frozen shoulder are poor posture can cause shortening of the ligaments around the shoulder joint tendonitis of rotator cuff, bicipital tendinitis, fractures, and dislocations around the shoulder etc.

Non shoulder causes: problems not related to shoulder joint like diabetes, cardio vascular diseases with referred pain to the shoulder, which keeps the joint immobile, reflex sympathetic dystrophy, frozen hand shoulder syndrome, a complication of colles fracture, can all read to frozen shoulder. The reason could be prolonger immobilization of the shoulder joint due to referred pain, etc.

CLINICAL FEATURES

- The patient complains of severe pain in the shoulder and upper arm of gradual and spontaneous onset.
- The patient demonstrates a capsular pattern of movement restriction.(i.e external rotation > abduction >internal rotation)
- Pain is noted at the end stage of stretch.
- Patient is unable to do routine daily activities like combing the hair, Women wearing the button of their blouse, doing overhead activities.
- Pain is often severe to disturb the sleep.

STAGES OF PERI ARTHRITIS:

Stage 1 (Stage of pain):

Patient complains of acute pain, decreased movements, external rotation gratest followed by loss of abduction and then forward flexion. Internal rotation is least affected. This stage lasts for 10-36 weeks.

Stage 2 (stage of stiffness):

In this stage, pain gradually decreases and the patient complains of stiff shoulder. slight movements are present. This lasts for 4-12 months.

Stage3 (stage of recovery):

Patient will have no pain and movements would have recovered but will never be regained to normal. It lasts for 6 months to 2 years.

TREATMENT

Conservative

Stage 1:

Anti- inflammatory drugs

Intra-articular steroids only for transient relief of pain only

Stage 2:

Both active and passive exercises are gradually begun followed by Physiotherapy, ultrasound, heat and shoulder wheel exercises.

Shoulder manipulation under general anaesthesia.

Stage 3:

Active and passive exercises, physiotherapy consisting of ultrasound etc are continued**.**

Surgery

Arthroscopic distension (Bruisement technique)

Arthroscopic release

DIFFERENTIAL DIAGNOSIS

Cervical spondylosis:

Cervical spondylosis, also known as cervical osteoarthritis or neck arthritis, is a common, age-related condition that affects the joints and discs in your neck. It develops from wear and tear of the cartilage and bones found in your cervical spine, which is in your neck. While it's largely due to age, it can be caused by other factors as well.

Impingement syndrome:

Shoulder impingement can be a painful condition that may cause a variety of medical issues. Patients may exercise pain in their shoulder, behind their back, and in their arms if they develop this condition. If a patient has a complete rotator cuff tear, then he may also experience weakness in the affected shoulder and arm.

Osteoarthritis of Acromioclavicular joints:

In its early stages, AC joint osteoarthritis usually causes pain and tenderness in the front of the shoulder around the joint. The pain is often worse when the arm is brought across the chest, since this motion compresses the joint. The pain is vague and may spread to include the shoulder, the front of the chest, and the neck. If the joint has been injured in the past, there may be a bigger bump over the joint on the affected shoulder than on the unaffected shoulder. The joint may also click or snap as it moves.

Prevention of Periarthritis shoulder:

"Prevention is better than cure". Anything you can do to prevent an injury from occurring is worth. Stretching and strengthening exercises are best defence against it.

INTERNAL MEDICINE

ELAM

Botanical name : *Elettaria cardamomum*

English name : Cardamom seeds

Family : Zingiberaceae

Organoleptic character:

Taste : Acrid

Potency : Hot

Division : Acrid

General properties:

தொண்டை கால்கவுள் தாலுகுதங்களில்
தோன்றும் நோவதிசாரம்பன்- மேகத்தால்
உண்டைபோல்எழுங் கட்டிகிரிச்சாரம்
உழலைவாந்திசிலந்திவிஷஞ்சுரம்
பண்டைவெக்கைவிதாகநோய் காசமும்
பாழுஞ் சோமப் பிணிவிந்துநட்டமும்
ஆண்டையீளைவன் பித்தம் இவைக்கெல்லாம்
ஆல மாங்கமழ் ஏலமருந்ததே

Action:

- Stimulant
- Carminative
- Stomachic
- Antispasmodic
- Tonic

Chemical constituents:

Alpha terpinyl acetate, Linalyl acetate, Limonen, Linalorl, Cineole, citronellol, nerol, transnerolidol

CHUKKU

Botanical name : *Zingiber officinale*

English name : Dried ginger

Family : Zingiberaceae

Organoleptic character:

Taste : Acrid

Potency : Hot

Division : Acrid

General properties:

சூலைமந்தம் நெஞ்செரிப்பு தோடமேப் பம்மழலை
மூலம் இரைப்பிருமல் மூக்குநீர் – வாலகப
தோடமதி சாரந் தொடர்வாத குன்மநீர்த்
தோடம்ஆ மம்போக்குஞ் சுக்கு.

-அகத்தியர் குணவாகடம்

Action:

- Stimulant
- Stomachic
- carminative

Chemical constituents:

Gingerin, Phellandrane, High flavonoid contents, polyphenols, tannin, isovanilin, adenine.

KOOGAINEERU

Botanical name	**:**	*Maranta arundinacea*
English name	**:**	Arrow root
Family	**:**	Marantaceae

Organoleptic character:

Taste : Sweet

Potency : Hot

Division : Sweet

General properties:

மேனியிடும் வாய்க்கு மிருதுவாம் ஆக்கியுண்ணத்
தானிருமல் வெப்பதிக தாகமிவை - ஏனிருக்கும்
அம்பே றிளங்கிழங்கி தியாவர்க்கு மாமணப்பூங்
கொம்பே கூகைக்கிழங்கைக் கூறு.

-அகத்தியர் குணவாகடம்

Action:

- Refrigerant
- Demulcent
- Nutrient

<u>THALISAPATHIRI</u>

Botanical Name	**:**	*Taxus buccata*
English Name	**:**	Flaurtiacalaphracta
Family	**:**	Taxaceae

Organoleptic Character

Taste	**:**	Acrid
Potency	**:**	Hot
Division	**:**	Acrid

பொது குணம்:

நாசி களப்பிணிகள் நாட்பட்ட - காசஞ்சு
வாசம் அருசி வனமங்கால் - வீசிவரு
மேகமந்தம் அத்திசுரம் விட்டேகுந் தாளிசத்தால்
ஆகுஞ் சுகப்பிரச வம்.

-அகத்தியர் குணவாகடம்

Actions:

- Carminative
- Stomachic
- Expectorant
- Tonic

SIRUNAAGAPOO

Botanical name **:** *Mesua nagassarium*

English name : Ceylon lorn wood

Family : Calophyllaceae

Organoleptic character:

Taste **:** Bitter, astringent

Potency **:** coolent

Division **:** Acrid

General characters;

சிறுநாகப் பூவினதுசெய்கைதனைச் சொல்வோம்
குறியாகும் மேகத்தைக் கொல்லும் - நெறிவிட்டுத்
தீதாய்ச் செல்வாயுவைந் தீர்க்குமிகுமற்போக்கும
கோதாய்!இதையறிந்துகொள

Action:

- Astringent
- Carminative
- Anti- inflammatory
- Anti pyretic

MILAGU

Botanical Name **:** *Piper nigrum*

English Name **:** Black pepper

Family **:** Piperaceae

Organoleptic Character

Taste **:** Bitter, Acrid

Potency **:** Hot

Division **:** Acrid

பொது குணம்:

“ தீயாகி யெங்கும் திரியுமதை யாவத்து
மோயாம லெப்படியு முண்டாக்காற்- பாயாது
போந்திமிர்வா தங்கிரந்தி புண்ணீரும் மண்ணவர்க்கும்
காந்திமெய்வா தச்சலுப்பைக் காய்

Chemical Constituents:

A volatile alkaloid Piperine or Pipirine 5-9%, Piperidine or Piperidin 5%, Abalsamic volatile essential 1-2%, fat7%.Mesocarp contains chavicin, a balsamic volatile oil, starch, gum, Piperrettine, Piperanine, PipericideSarmentine, Eugenol.

Ref: Indian Herbal Pharmacopoeia, P – 321.

Actions:

- Carminative
- Pungent
- Antiperiodic
- Analgesic
- Anti- inflammatory
- Antioxidant
- Cyclo oxygenase inhibitory activity

Ref: Indian Herbal Pharmacopoeia, P – 324 Database, Vol. – 190.

KIRAMBU

Botanical name **:** *Syzygium aromaticum*

English name **:** Cloves, Clove tree

Family **:** Myrtaceae

Organoleptic character

Taste : Acrid

Potency : Hot

Division : Acrid

General properties:

பித்த மயக்கம் பேதியொடு வாந்தியும்போம்
சுத்தவிரத்தக் கடுப்புந் தோன்றுமோ - மெத்த
இலவங்கங் கொண்டவருக்கேற் சுகமாகும்
மலமங்கே கட்டுமென வாழ்த்து.

- அகத்தியர் குணவாகடம்.

Chemical constituents:

Essential oils mainly contain euginol, euginyl acetate, β-caryophiline.

Action:

- Antispasmodic
- Carminative
- Stomachic

SUGAR

Botanical name **:** *Saccharum officinarum. Linn*

English name **:** Sugar cane

Family **:** Poaceae

Organoleptic character

Taste : Sweet

Potency : Coolent

Division : Sweet

General properties:

சீனிச் சர்க்கரைக்குத் தீராத வன்சுரமுங்
கூனிக்கும் வாதத்தின் கூட்டுறவும் - ஏனிருக்கும்
வாந்தி யொடுகிருமி மாறாத விக்கலுமே
போந்திசையை விட்டுப் புரண்டு.

- அகத்தியர் குணவாகடம்.

Action:

- Antiseptic
- Demulcent

EXTERNAL MEDICINES

NATHAI CHOORI

Botanical name : *Spermacoce hispida*

English name **:** shaggy button weed

Family : Rubiaceae

Organoleptic character:

Taste **:** sweet, astringent

Potency **:** Coolent

Division **:** sweet

Action:

- Alterative
- Tonic
- Anti- inflammatory
- Hypolipidaemic

Alkaloids:

- Borreline
- Beta-sitostero
- Ursolic acid
- Iso-rhamnesin

VASAMBU

Botanical name: *Acorus calamus*

English name : Sweet flag

Family : Araceae

Organonoleptic character:

Taste : Acrid

Potency : Hot

Division : Acrid

General properties:

பாம்பாதி நஞ்சாற் புதப்புண் வலிவிடபாகங் குன்மம்
சூம்பா ரிரத்தபித் தம்முக நாற்றம்வன் சூலைசன்னி
வீம்பாம்பை காசம் பிலீகஞ் சிலிபதம் வீறிருமல்
தாம்பாங் கிருமி யிவையேகு மாசிவ சம்பினையே.

- தேரையர் குணவாகடம்

Action:

- Stimulant
- Stomachic
- Antispasmodic
- Carminative
- emetic
- disinfectant

Alkaloids:

- Acorin
- Acoretin
- Calamin
- Starch
- Calamen
- Calamenol
- Asarone

POONDU

Botanical name: *Allium sativum*

English name :Garlic

Family : Alliaceae

Organoleptic character:

Taste : Acrid

Potency : Hot

Division : Acrid

ACTION:

- Carminative
- Stomachic
- Tonic
- Alterative
- Stimulant
- Expectorant
- Diuretic

Chemical constituents

- Allicin
- Allisatin

AAMANAKU

Botanical name : *Ricinus communis*

English name : Castor oil plant

Family : Euphorbiceae

Organoleptic character:

Taste : Bitter

Potency : Hot

Division : Acrid

General properties:

வாதத் தொடக்கை வரவொட்டா மற்படிக்கு
காதத்துக் கப்பாற் கடியுமே - சூதத்தைப்
பேரண்டப் பந்திக்கும் பேதிக்கு நோய்க்காட்டை
யேரண்ட மென்ப தினியே.

- தேரையர் வெண்பா

Action:

- Anti vatha
- Laxative
- Emollient

Alkaloids:

- Ethanol
- Ethyl ester
- Triethyl citrate
- Octadecanic acid

INTERNAL MEDICINE- RAJA ELATHY CHOORANAM

MILAGU- Piper nigrum

KIRAMBU-Syzygium aromaticum

CHUKKU- Zingiber officinalis

ELAM- Elattaria cardamum

SUGAR

SIRUNAGAPPO- Mesua nagassarium

KOOGAINEER-Maranta Arundinaceae

THALISAPATHRI- Taxus buccata

EXTERNAL MEDICINE- NATHAICHOORI ENNAI

VELLULI- Allium sativum

VASAMBU- Acorus calamus

AMANAKKU - Riccinus communis

NATHAICHOORI

Spermacoce hispida

TRIAL DRUGS

Rajaelathy chooranam

Nathaichoori Ennai

MATERIALS AND METHODS

STANDARD OPERATING PROCEDURE:

Source of trial medicine:

The required raw drugs for the trial medicines will be purchased from a well reputed country raw drug shop then raw drugs will be authenticated by the department of Medicinal botany National Institute of Siddha. Authenticated raw drugs will be purified separately and then the trial drugs will be prepared as per the literature in Gunapadam Laboratory of National Institute of Siddha.

PREPARATION OF TRIAL DRUGS

Internal Drug: RAJAELATHY CHOORNAM

INGRIDIENTS

- Elam (Fruit of *Elattaria cardomomum*) - 64 Varagan eadai (269gm*)*
- Chukku (Rizome of *Zingeber officinale*) - 32 Varagan eadai (134.4gm)
- Koogai neer (Tuber of *Maranta arundinaceae*) - 16 Varagan eadai (67.2gm)
- Thalisabathri (*Abies spectabilis*) - 8 Varagan eadai (34gm)
- Serunaga poo (Flower of *Mesuna nagassarium*) - 4 Varagan eadai (17gm)
- Milagu (Fruit of *Piper nigrum*) - 2 Varagan eadai (8.4gm)
- Kirambu (Flower of *Syzygium aromaticum*) - 1 Varagan eadai (4.2gm)
- Sugar - 1 ½ saer (420gm)

PURIFICATION OF RAW DRUGS:

Purification of Chukku: Soak in lime stone water and dry it in shade then peel off the outer layer [Ref: Sarakugalin Suthee Muraigal, Pg .6]

Purification of Milagu: Soak in butter milk for a period of 1 saamam (3 hours) then allow it to dry. [Ref: Sikicha Rathina Deepam Ennum Vaithiya Nool, Page 28]

Purification of Kirambu: Dry it in sunlight and fry. [Ref: Sarakugalin Suthee Muraigal Page: 6]

Purification of Thalisabathri: Dry it in sunlight. [Ref: Sikicha Rathina Deepam Ennum Vaithiya Nool, Page 28]

Purification of Sirunagapoo: Dry it in sunlight. [Ref: Sikicha Rathina Deepam Ennum Vaithiya Nool, Page 28]

Purification of Elam: Dry it in sunlight and fry. [Ref: Sarakugalin Suthee Muraigal, Page:6]

Purification of koogai kilangu : Dissolve in pure water for 7 times and filter it and dry it in sunlight. [Ref : Sikicha Rathina Deepam Ennum Vaithiya Nool.

PREPARATION OF INTERNAL DRUG:

METHOD OF PREPARATION:

After purification of raw drugs powder them individually and then mix well together and finally add sugar.

EXTERNAL DRUG

Nathaichoori ennai:

INGRIDIENTS:

- Nathai choori vear (Root *of Spermacoce hispida*) - 3palam (105gm)
- Vasampu (Rhizome of *Acorus calamus*) - ¾ palam (12gm)
- Poondu (Bulb of *Allium sativum*) - ¼ palam (8.75gm)
- Amanakku ennai (Oil of *Ricinus communis*) - 1 padi (1.34litre)

Method of preparation:

Grind the raw drugs mix it with castor oil and heat it until attaining suitable consistency.

Drug storage:

The drug Rajaelathy Chooranam is stored in a clean glass jar and Nathai choori Ennai is stored in a clean and dry narrow mouthed bottles.

Dispensing:

The Rajaelathi Chooranam was given in packets and Nathai choori ennai was given in bottles.

Varmam Points to be applied for the Patient:

Kavuli Kaalam

Vellai varmam

Kaipuja poruthu varmam

PRECLINICAL STUDY

CHEMICAL EVALUATION

Experimental procedure:

5 g of *Rajaelathy Chooranam* was taken in a 250 ml of clean beaker and 50ml of distilled water was added to it. Then it was boiled well for about 10 min. Then it is allowed to cool and filtered in a 100 ml volumetric flask and made up to 100 ml with distilled water. This preparation is used for the qualitative analysis of acidic/basic radicals and biochemical constituents in it.

Preparation of extract:

5gm of *Rajaelathy Chooranam* is weighed accurately and placed in a 250ml clean beaker and 50ml of distilled water was added with it. Then it was boiled well for about 10 minutes. Then it was allowed to cool and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. The bio-chemical analysis of *Rajaelathy Chooranam* was done at Biochemistry lab, National Institute of Siddha, Chennai-47.

Preliminary test for Copper, Sodium, Silicate and Carbonate:

Test for Silicate:

a. A little (500mg) of the sample is shaken well with distilled water.

b. A little (500mg) of the sample is shaken well with con. HCl/Con. H_2So_4.

Action of Heat: A small amount (500mg) of the sample is taken in a dry test tube and heated gently at first and then strong.

Action of Heat: A small amount (500mg) of the sample is taken in a dry test tube and heated gently at first and then strong.

Flame Test: A small amount (500mg) of the sample is made into a paste with con. HCl in a watch glass and introduced into non-luminous part of the Bunsen flame.

Ash Test: A filter paper is soaked into a mixture of sample and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited.

Test For Acid Radicals

Test For Sulphate: 2ml of the above prepared extract was taken in a test tube and 2ml of 4% dil. ammonium oxalate solution was added.

Test For Chloride: 2ml of the above prepared extracts was added with 2ml of dil-HNO_3 until the effervescence ceases off. Then 2 ml of silver nitrate solution was added.

Test For Phosphate: 2ml of the extract was treated with 2ml of con.HNo3 and 2ml of dil. ammonium molybdate solution.

Test For Carbonate: 2ml of the extract was treated with 2ml dil. magnesium sulphate solution

Test For Nitrate: 1gm of the substance was heated with copper turning and concentrated H_2SO_4 and viewed the test tube vertically down.

Test For Sulphide: 1gm of the substance was treated with 2ml of con. HCL

Test For Fluoride & Oxalate: 2ml of extract was added with 2ml of dil. Acetic acid and 2ml dil.calcium chloride solution and heated**.**

Test For Nitrite: 3drops of the extract was placed on a filter paper, on that-2 drops of dil.acetic acid and 2 drops of dil. Benzidine solution were placed.

Test For Basic Radicals

Test For Lead: 2ml of the extract was added with 2ml of dil.potassium iodine solution.

Test For Copper: One pinch (50mg) of substance was made into paste with con. HCl in a watch glass and introduced into the non-luminous part of the flame.

Test For Aluminium: In the 2ml of extract dil.sodium hydroxide was added in 5 drops to excess.

Test For Iron:

a. To the 2ml of extract add 2ml of dil. ammonium solution

b. To the 2ml of extract 2ml thiocyanate solution and 2ml of con HNo3 is added

Test For Zinc: In 2ml of the extract dil.sodium hydroxide solution was added in 5 drops to excess and dil.ammonium chloride was added.

Test For Calcium: 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution

Test For Magnesium: In 2ml of extract dil.sodium hydroxide solution was added in drops to excess.

Test For Ammonium: In 2ml of extract 1 ml of Nessler's reagent and excess of dil. sodium hydroxide solution were added.

Test For Potassium: A pinch (25mg) of substance was treated with 2ml of dil. sodium nitrite solution and then treated with 2ml of dil. cobalt nitrate in 30% dil.glacial acetic acid.

Test For Sodium: 2 pinches (50mg) of the substance was made into paste by using HCl and introduced into the blue flame of Bunsen burner.

Test For Mercury: 2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.

Test For Arsenic: 2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.

Other constituents

Test For Starch: 2ml of extract was treated with weak dil. iodine solution

Test For Reducing Sugar: 5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes.

Test For The Alkaloids:

a) 2ml of the extract is treated with 2ml of dil. potassium iodide solution.
b) 2ml of the extract is treated with 2ml of dil.picric acid.

Test For Tannic Acid: 2ml of extract was treated with 2ml of dil. ferric chloride solution

Test For Unsaturated Compound: In the 2ml of extract 2ml of dil. Potassium permanganate solution was added.

Test For Amino Acid: 2 drops of the extract was placed on a filter paper and dried well, and then 20ml of Burette reagent was added in it.

TOXICITY STUDIES OF *RAJAELATHY CHOORANAM*

To evaluate the safety profile of Raja elathy chooranam short term and long term toxicity study carried out as followed. The principles of laboratory animal care were followed and the Institutional Animal Ethical Committee approved the use of animals and the study design. IAEC registered and approval number: (IAEC). (NIS/IAEC/III/07/29092016 dated 29.09.2016) for Short term toxicity study and Long term toxicity study.

Experimental Animals:

Species	:	Wistar albino Rats
Sex	:	Male and Female
Age/weight at start of test	:	6 weeks/140-160g b.wt
Acclimatization Period	:	7 days prior to dosing
Housing	:	Polypropylene cages with bedding with husk.

Husbandry	:	12-h light/12-h dark cycle/ Room temperature 22°C±3°C and relative humidity 30–70%
Feed and Water	:	Rodent pelleted feed RO purified water ad *libitum*
Identification	:	Animals will be kept in Polypropylene cages and numbered

Experimentation Details of Short term Toxicity Study:

Groups/Treatment regimen	:	Grouped by randomisation
Test Guideline	:	WHO
Length of exposure to test substance	:	1 day
No of Animals	:	5 Female+ 5 Male / group
Control group	:	Vehicle (water)
Test groups	:	*Rajaelathy Chooranam*2000 mg/kg.b.wt

The wistar albino rats of both sex weighing 150-200g will be obtained from authorized animal breeders of animal laboratory in TANUVAS, Madavaram, Chennai and stocked in animal house at National Institute of Siddha, Chennai. Animals will be house in cage at 22°C±3°C andrelative humidity 30–70% and have free access to standard rat pellet diet (Sai Meera Foods Pvt. Ltd., Bangalore). The animals will be dosed with *Rajaelathy chooranam* by oral for one day and monitored for behavioural parameters for the first 4 hours after drug administration. Body weight of the animal will be monitored at weekly intervals. The animals that the die within this period will be subjected to necropsy. Remaining animals will be weighed and sacrificed under the injection of Pentathal Sodium on the 15^{th}day of the Study period. The toxicological effects were assessed on the basis of mortality.

Preparation of Test Drug Doses:

Groups	No. of Rat
Group I: Vehicle control (water)	10 (5M+5F)
Group II: test drug (RC)- 2000 mg/kg b.wt	10 (5M+5F)

***RC**- *Rajaelathy chooranam*

Route of administration

Oral route were selected because it is the normal route of clinical administration.

Administration of Dose

The animals were kept in fasting (only food was with held) for12hrs and weighed prior to dosing. Three animals were used for each step. A single dose of the solution (2000mg/kg) was consecutively administered by oral gavage using intubation cannula. Food was with held for another 4hrs after dosing and administration of drug. As per the guide line the starting dose level was taken as 2000mg/kg bodyweight.

Observations:

Observations were made and recorded systematically and continuously observed after the substance administration as per the guidelines.

- ✓ ½ hour, 1 hour, 2 hour, 4 hour and upto 24 hours observation.
- ✓ All rats will be observed twice daily on week days for 14 days.
- ✓ Body weight per weekly one times.
- ✓ Feed intake per day

Cage side observation

The animals were monitored for behavioral parameters like, Alertness, Aggressiveness, piloerection, Grooming, Gripping, Touch Response, Motor Activity, Tremors, Convulsions, Muscle Spasm, Catatonia, Muscle relaxant, Hypnosis Analgesia, Lacrimation, Exophthalmos, Diarrhea, Writhing, Respiration, Mortality

Necropsy:

Necropsy includes gross examinations of the external surface of the body, all orifices, cranial, thoracic and abdominal cavities and their contents. Brain, eye, lungs, heart, spleen, liver, kidneys, adrenals and uterus of all animals.

Experimentation Details of Long term Toxicity Study:

Experimental Animals:

Species	:	Wistar Albino Rats
Sex	:	Male and Female
Age/weight at start of test	:	6 weeks/140-160g b.wt
Acclimatization Period	:	7 days prior to dosing
Housing	:	Polypropylene cages with bedding with husk
Husbandry	:	12-h light/12-h dark cycle/ Room temperature 22°C±3°C and relative humidity 30–70%
Feed and Water	:	Rodent pelleted feed RO purified water ad *libitum*
Identification	:	Animals will be kept in Polypropylene cages and numbered

Experimentation Details of Long term Toxicity Study:

Groups/Treatment regimen	:	Grouped by randomisation
Test Guideline	:	WHO
Length of exposure to test substance	:	90 days
No of Animals	:	10 Female+10 Male / group
Control group	:	Vehicle (water)
Test groups	:	*Rajaelathy Chooranam* (Low dose, Mid dose, High dose)

The 80 Wistar albino rats of both sex selected randomly. The animals were divided into four groups. Each group consist at 20 animals.

First group treated as vehicle control and second, third and fourth groups were treated with *Rajaelathy chooranam* Low dose (180 mg), Mid dose (900 mg) and High dose (1800 mg) respectively. The animals were dosed with *Rajaelathy chooranam* by oral for 90 days and is monitored for behavioural parameters for the first 4 hours after drug administration. Body weight of the animal was be monitored at weekly intervals. The animals that die within this period was be subjected to necropsy. Remaining animals was be weighed and sacrificed under the injuction of Pentathal Sodium on the on the 91st day of the study. Blood will be collected from the anesthetized animals from Abdominal aorta and the following investigations like Haematology, Biochemical analysis and Histopathology are done.

They above dose were fixed from the result of Short term toxicity study

Groups	No. of Rats
Group I: Vehicle control (water)	20(10M+10F)
GroupII:Test drug (*RC*)- low dose (180mg/kg b.wt)	20(10M + 10F)
GroupIII: Test drug(*RC*) - Mid dose (900mg/kg.b.wt)	20(10M +10F)
GroupIV:Test drug(*RC*) High dose (1800 mg/kg b.wt)	20(10M +10F)

***RC-** *Rajaelathy chooranam*

Preparation and administration of dose:

Rajaelathy Chooranam was dissolved in water to obtain concentrations of 1800mg/ml. It was administered to animals at the dose levels of180mg/kg b.wt, 900mg/kg b.wtand1800mg/kg b.wt. The test substance solutions were freshly prepared every two days once for 90days. The control animals were administered with water as vehicle. Administration was given by oral, once daily for 90 consecutive days.

Observations:

Experimental animals were kept under observation throughout the course of study For the following

- ✓ All rats will be observed twice daily on week days for 90 days
- ✓ Body weight per weekly one times
- ✓ Feed intake per day

Cage side observation

The animals were monitored for behavioral parameters like, Alertness, Aggressiveness, pilo erection, Grooming, Gripping, Touch Response, Motor Activity, Tremors, Convulsions, Muscle Spasm, Catatonia, Muscle relaxant, Hypnosis Analgesia, Lacrimation, Exophthalmos, Diarrhea, Writhing, Respiration, Mortality.

Gross necropsy:

Gross necropsy includes examinations of the external surface of the body, all orifices, cranial, thoracic and abdominal cavities and their contents. Brain, eye, lungs, heart, spleen, liver, kidneys, adrenals and uterus of all animals.

Laboratory Investigations:

On the 91st day, the animals were fasted over night, then anesthetized to collect blood samples from the abdominal aorta in two tubes: one with EDTA for the hamatological parameters, another one without any anti coagulant and was centrifuged at 4000rpm at4°C for10minutes to obtain these rum for biochemical parameters.

***Hematological Investigations*:**

Blood samples of control and experimental rats were analyzed for hemoglobin (Hb), total red blood corpuscles (RBC), white blood corpuscles (WBC) count, Mean corpuscular volume (MCV), Mean corpuscular hemoglobin (MCH) were calculated.

***Biochemical Investigations*:**

Serum samples of control and experimental rats were analyzed for Bilirubin, Uric Acid, Creatinine, Triglyceride, Total Cholesterol, HDL, LDL, VLDL, using standard methods. Activities of glutamate oxalo acetate transaminase / Aspartate amino transferase (GOT/AST) and glutamate pyruvate transaminase / Alanine amino transferase (GPT/ALT) were estimated as perthe colorimetric procedure.

Necropsy:

All the animals were sacrificed on the 91st day. Necropsy of all animals was carried out and the weights of the organs including liver, kidneys, spleen, brain, heart, lungs and stomach were recorded.

Histopathology:

The organs included liver, kidneys, spleen, brain, heart, lungs and stomach of the animals were preserved, and they were subjected to histo-pathological examination.

Histo-pathological investigation of the vital organs was done. The organ pieces (3-5umthick) of the three different (low, mid, high) dose level was preserved and was fixed in 10% formalin for 24 had washed in running water. Samples were dehydrated in an auto technique on and then cleared in benzene to remove absolute alcohol. Embedding was done by passing the cleared samples through three cups containing molten paraffin at 50^{o}C and then in a cubical block of paraffin made by the "L" molds. It was followed by microtome and the slides were stained with Haematoxylin-eosin.

CLINICAL STUDY

Study design:

Study Type	:	An open clinical trail
Study Place	:	OPD and IPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai - 47.
Study Period	:	18 Months
Sample Size	:	40 patients (Both IPD & OPD)

Subject Selection:

Patients reporting with symptoms of *Kumbavaatham* will be subjected to screening using screening proforma then they will be involved for the trial by fulfilling the inclusion criteria.

Inclusion Criteria:

- Age : 20-65yrs
- Sex : Both male and female
- Pain and stiffness in shoulder region
- Restricted movements of shoulder joint
- Exacerbation of pain on movement
- Restricted movements of shoulder joint(abduction and external rotation)
- With or without pain radiating to upper arm
- Patients willing undergo radiological investigation and give blood samples for laboratory investigations
- Patient willing to sign the informed consent stating that he/she will consciously stick to the treatment but can opt out of the trial of his/her own conscious discretion.

Exclusion Criteria:

- Diabetes Mellitus
- Pregnancy and lactation
- Cardiac disease
- Septic arthritis
- Malignant hypertension
- Gonococcal arthritis
- Fracture and dislocations of shoulder joint
- Cervical spondylosis
- Any other chronic illness

Withdrawal Criteria:

- Intolerance to the drug and development of adverse reactions during drug trial.
- Poor patient compliance and defaulters.
- Patient turning unwilling to continue in the course of clinical trial.

Tests and Assessments:

A. Clinical assessment

B. Laboratory Investigations

C. Radiological investigations

D. Siddha system examination

A. Clinical Assessment

- Pain and stiffness in Shoulder joint.
- With or without radiation of pain to upper arm.
- Exacerbation of pain on movements.
- Restricted movements [abduction and external rotation]

B. LABORATORY INVESTIGATIONS:

BLOOD:

- H B
- Total WBC Count
- DC - Polymorphs:
  Lymphocytes
  Eosinophils
  Monocytes
  Basophils
- Total RBC count
- ESR ½ hr:
  1hr:
- Blood sugar - Fasting :
  Post prandial:

Serum cholesterol, uric acid

CRP, RA factor, ASO titre

RENAL FUNCTION TESTS:

Blood Urea

Serum Creatinine

LIVER FUNCTION TESTS:

Serum total bilirubin, Direct bilirubin & Indirect bilirubin

Serum Alkaline phosphatase

SGOT & SGPT

URINE:

Urine sugar – Fasting & Post prandial:

Albumin

Deposits

D. RADIOLOGICAL INVESTIGATION

X - Ray Shoulder joint: AP View.

SIDDHA PARAMETERS:

1. Naadi
2. Sparisam
3. Naa
4. Niram
5. Mozhi
6. Vizhi
7. Malam
8. Moothiram

DATA COLLECTION FORMS:

Required information will be collected from each patient by using the following forms:

FORM I	: Screening and Selection form
FORM II	: Clinical Assessment form
FORM III	: Laboratory Investigation form
FORM IV	: Drug compliance form
FORM V	: Patient information form
FORM VI	: Informed consent form
FORM VII	: Withdrawal / Pharmaco vigilance / adverse form
FORM VIII	: Dietary Advice form

STUDY ENROLLMENT:

Patients reporting at the OPD with the clinical symptoms of **Kumbavatham** were examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who were enrolled would be informed (Form V) about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and informed consent would be obtained in writing from them in the consent form (Form VI).

Complete clinical history, complaints and duration, examination findings and laboratory investigations recorded in the prescribed Proforma. Screening Form-I were filled up: Form – II and Form – III will be used for recording the patient history, clinical examination of symptoms, signs and laboratory Investigation. If there any abnormal Laboratory Reports obtained then excluded from the study.

Patients were advised to take the trial drug and to follow the appropriate dietary advice. (Form -VIII)

CONDUCT OF THE STUDY:

Purgation with Meganaatha Kuligai - 2 early morning with Hot Water given for balancing the deranged Mukuttram before starting the treatment.

(Ref: Siddha formulary of India. Part- I)

Next day onwards the trial drug, **Rajaelathy Chooranam** (Internal) and **Nathaichoori Ennai** (external) given continuously for 48 days. OPD patients are requested to visit the hospital once in 7 days. In each and every visit clinical assessment is done and prognosis was noted in the Prescribed Proforma. For IPD Patients clinical assessment was done daily. 20 patients were given Varmam treatment along with trial medicines and the remaining 20 were given medicine only. If there is need of IPD patients admitted in the ward for the clinical assessment. Laboratory investigations and Radiological investigations are done before and after the trial. At the end of the treatment, the patient advised to visit the OPD for follow-up. Defaulters not be allowed to continue and be withdrawn (Form VII) from the study.

DATA ANALYSIS:

After enrolling the patient for the study, a separate file for each and every patient opened and all forms kept in the file. Study No and Patient No written on the top of file for easy identification. Whenever the patient visits OPD during the study period, the respective patient's file taken and necessary entries made at the assessment form or other suitable form. The screening forms filed separately. The data recordings monitored for completion and adverse event by HOD and pharmaco - vigilance committee. All forms were scrutinized in presence of Investigators by Sr.Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias.

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT

In this study, no adverse reactions were observed during the course of treatment.

DATA ANALYSIS:

After enrolling the patients in the study, a separate file for each patient maintained and all forms kept in the file. Study No and patient's No entered on the top of the file for easy identification. Whenever the patients visit OPD during the study period, necessary entries made at the assessment forms. The screening forms filled separately.

All forms were scrutinized by Senior Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias.

OUTCOME:

Shoulder improvement assessed by following assessment:

Shoulder Pain and disability index (SPADI)

Source:

Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a shoulder pain and disability index. Arthritis Care Res. 1991 Dec;4(4):143-9.

The Shoulder Pain and Disability Index (SPADI) is a self-administered questionnaire that consists of two dimensions, one for pain and the other for functional activities.

The pain dimension consists of five questions regarding the severity of an individual's pain. Functional activities are assessed with eight questions designed to measure the degree of difficulty an individual has with various activities of daily living that require upper-extremity use. The SPADI takes 5 to 10 minutes for a patient to complete and is the only reliable and valid region-specific measure for the shoulder.

SCORING INSTRUCTIONS

To answer the questions, patients place a mark on a 10cm visual analogue scale for each question. Verbal anchors for the pain dimension are ‘no pain at all’ and ‘worst pain imaginable’, and those for the functional activities are ‘no difficulty’ and ‘so difficult it required help’. The scores from both dimensions are averaged to derive a total score.

INTERPRETATION OF SCORES

Total pain score: / 50 x 100 = %

(Note: If a person does not answer all questions divide by the total possible score, eg. if 1 question missed divide by 40)

Total disability score: / 80 x 100 = %

(Note: If a person does not answer all questions divide by the total possible score, eg. if 1 question missed divide by 70)

Total Spadi score: / 130 x 100 = %

(Note: If a person does not answer all questions divide by the total possible score, eg. if 1 question missed divide by 120)

The means of the two subscales are averaged to produce a total score ranging from 0 (best) to 100 (worst).

Minimum Detectable Change (90% confidence) = 13 point

(Change less than this may be attributable to measurement error)

Shoulder Pain and Disability Index (SPADI)

Please place a mark on the line that best represents your experience during the last week attributable to your shoulder problem.

PAIN SCALE

How severe is your pain? Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable

At its worst?	0	1	2	3	4	5	6	7	8	9	10
When lying on the involved side?	0	1	2	3	4	5	6	7	8	9	10
Reaching for something on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Touching the back of your neck?	0	1	2	3	4	5	6	7	8	9	10
Pushing with the involved arm?	0	1	2	3	4	5	6	7	8	9	10

DISABILITY SCALE

How much difficulty do you have?

Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help.

Washing your hair?	0	1	2	3	4	5	6	7	8	9	10
Washing your back?	0	1	2	3	4	5	6	7	8	9	10
Putting on an undershirt or jumper?	0	1	2	3	4	5	6	7	8	9	10
Putting on a shirt that buttons down the front?	0	1	2	3	4	5	6	7	8	9	10
Putting on your pants?	0	1	2	3	4	5	6	7	8	9	10
Placing an object on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Carrying a heavy object of 10 pounds (4.5 kilograms)	0	1	2	3	4	5	6	7	8	9	10
Removing something from your back pocket?	0	1	2	3	4	5	6	7	8	9	10

OUTCOME:

- **Very Good –**76-100% reduction of SPADI Score
- **Good –** 51-75% reduction in SPADI Score
- **Moderate –** 26-50% reduction in SPADI Score
- **Mild –** 0-25% SPADI Score

QUALITATIVE ANALYSIS

PHYSICO-CHEMICAL ANALYSIS

Table-1: Colour, nature of Rajaelathy Chooranam

S.no	Parameters	Results	Method of Testing
1.	Colour	Yellowish green	By visual
2.	Odour	Odour(Sweet Smell)	Olfactory examination
3.	Solublity	• Soluble in honey • Insoluble in water	Qualitative
4.	Nature	Powder	By visual

Table-2: Test for Basic radicals

S.no	Procedures	Rajaelathy Chooranam
1.	Test for Ammonium	-
2.	Test for Sodium	-
3.	Test for Magnesium	-
4.	Test for Aluminium	-
5.	Test for Potassium	+

6.	Test for Calcium	+
7.	Test for Ferrous iron	+
8.	Test for Copper	-
9.	Test for Zinc	-
10.	Test for Arsenic	-
11.	Test for Mercury	-
12.	Test for Lead	-

Inference

Bio-chemical analysis for basic radicals reveals that Rajaelathy Chooranam contains Potassium, Calcium and Iron.

Table-3: Test for Acidic radicals

S.no	**Procedures**	Rajaelathy Chooranam
1.	Test for Sulphate	+
2.	Test for Chloride	+
3.	Test for Phosphate	+

4.	Test for Flouride & Oxalate	-
5.	Test for Nitrite	+

Table-4: Test for Acidic radicals

S.no	**Procedures**	Rajaelathy Chooranam
1.	Test for Starch	+
2.	Test for Reducing sugar	+
3.	Test for Alkaloids	+
4.	Test for Amino acids	_
5.	Test for Tannic acids	+
6.	Test for type of compounds	No Change

Inference

Bio-chemical analysis for acid radicals reveals that Rajaelathy Chooranam contains Chloride, sulphide, phosphate, nitrite Starch, Reducing sugar, Alkaloid, tannic acid.

Toxicity study Results of Rajaelathy Chooranam

Table: 5 Dose finding experiment and its behavioural Signs of Toxicity

No	Dose Mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	Control	+	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-
2.	2000	+	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-

1.Aletness 2.Aggressiveness 3.pilo erection 4.Grooming 5.Gripping 6.Touch Response 7. Motor Activity 8.Tremors 9.Convulsions 10.Muscle Spasm 11.Catatonia 12.Muscle relaxant 13.Hypnosis 14.Analgesia 15.Lacrimation 16.Exophthalmos 17.Diarrhoea 18.Writhing 19. Respiration 20.Mortality

\+ Presence of Activity

\- Absence of Activity

All the data were summarized in the form of table revealed no abnormal signs and behavioural changes in rats at the dose of 2000 mg/kg body weight administered orally

Short term Toxicity study

In short term toxicity study, the test drug at Rajaelathy Chooranam for single dose(2000mg/kg b.wt) was administered.

There was no mortality or signs of toxicity observed after dosing Rajelathy Chooranam 2000mg/kg body weight during the study period of 14 days. This indicates that the LD50 of Rajaelathy Chooranam is more than 2000mg/kg b.wt.

There was no changes in skin and fur, eyes and mucous membranes of all animals. The eating, drinking habit, sleep pattern, locomotion were normal in all animals and no changes in body weight as compared to control group.

At the end of the 14th day necropsy was done and there was no abnormality seen in test groups as compared to control group during the examination.

Long term Toxicity study

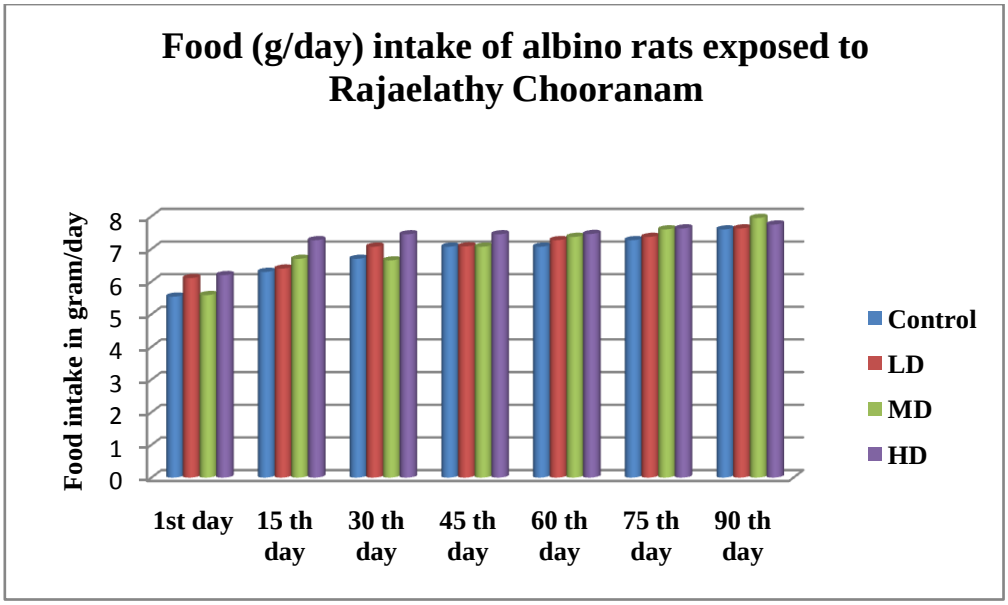
Haematological report:

There is no significant changes in haematological and serological parameters of the control and test group after the administration of trial drug.

Food (g/day) intake of albino rats exposed to Rajaelathy Chooranam

Dose (mg/kg/da	Control	LD	MD	HD
1st day	5.54±0.21	6.11±0.21	5.59±0.25	6.2±0.15
15 th day	6.3±0.18	6.4±0.21	6.7±0.27	7.27±0.27
30 th day	6.7±0.27	7.07±0.17	6.65±0.18	7.45±0.24
45 th day	7.07±0.17	7.08±0.18	7.07±0.17	7.45±0.25
60 th day	7.07±0.17	7.27±0.27	7.37±0.24	7.45±0.25
75 th day	7.27±0.27	7.37±0.24	7.60±0.28	7.63±0.25
90 th day	7.60±0.28	7.63±0.25	7.95±0.11	7.75±0.13

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

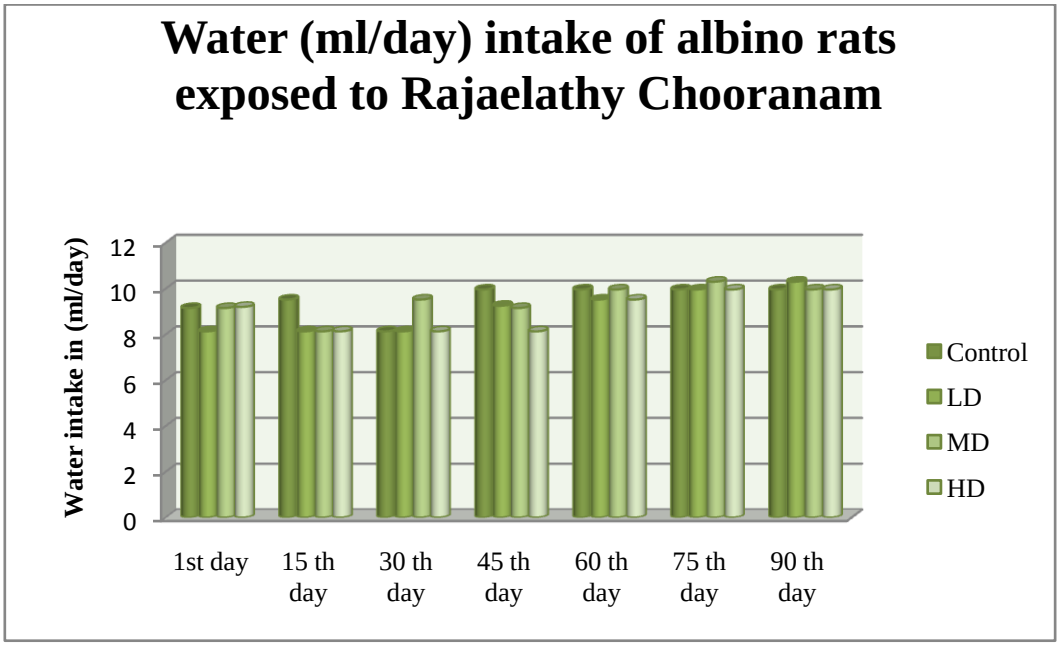


Water (ml/day) intake of albino rats exposed to Rajaelathy Chooranam

Dose (mg/kg/day)	Control	LD	MD	HD
1st day (ml/rat)	9.15±0.13	8.13±0.12	9.15±0.12	9.20±0.15
15 th day (ml/rat)	9.52±0.21	8.13±0.12	8.13±0.12	8.13±0.12
30 th day (ml/rat)	8.13±0.12	8.13±0.12	9.52±0.21	8.13±0.12
45 th day (ml/rat)	9.96±0.11	9.25±0.17	9.15±0.12	8.13±0.12
60 th day (ml/rat)	9.96±0.11	9.52±0.21	9.96±0.11	9.52±0.21

75 th day (ml/rat)	9.96±0.11	9.96±0.11	10.30±0.13	9.96±0.11
90 th day (ml/rat)	9.96±0.11	10.30±0.13	9.96±0.11	9.96±0.11

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

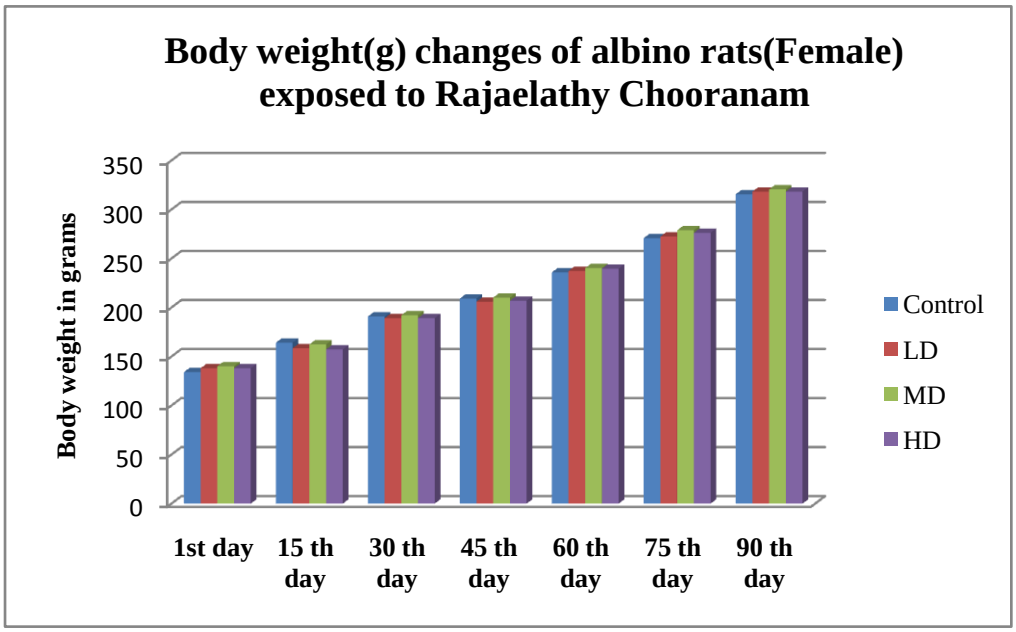


Body weight (g) changes of albino rats (female) exposed to Rajaelathy Chooranam

Dose (mg/kg/day)	**Control**	**LD**	**MD**	**HD**
1st day	134.16±4.21	138.12±3.50	140.2±2.13	138.14±2.46

15 th day	164.16±4.21	158.45±2.16	162.36±5.07	157.25±1.67
30 th day	190.83±6.14	189.16±6.23	192.12±4.21	189.25±5.26
45 th day	209.16±5.07	206±4.21	210.2±6.30	207±3.16
60 th day	235.83±4.21	237.38±6.14	240.24±6.14	239.68±4.21
75 th day	270.83±6.30	272.5±5.02	278.8±2.36	276.26±6.24
90 th day	315.5±6.44	318.24±6.12	320.6±5.07	318.28±1.36

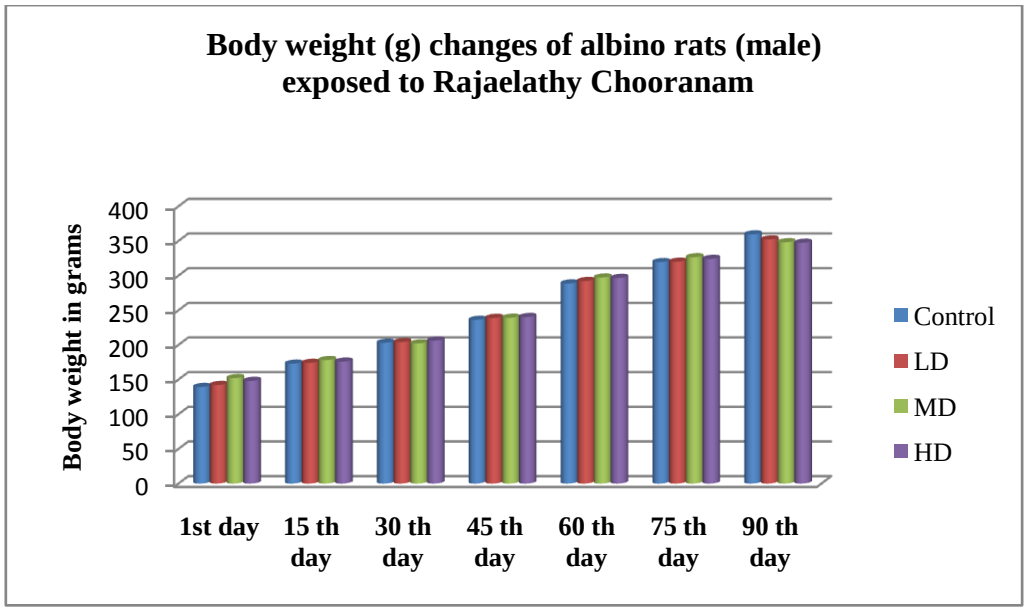
Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12



Body weight (g) changes of albino rats (male) exposed to Rajaelathy Chooranam

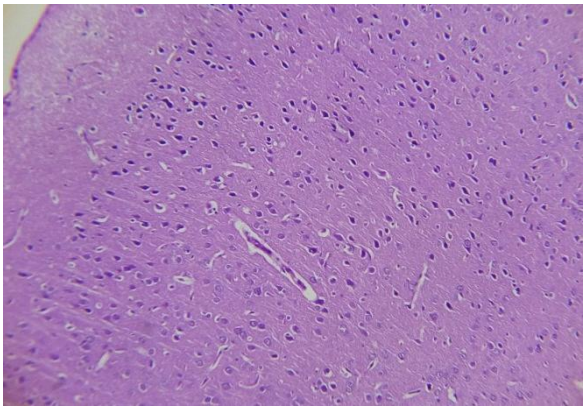
Dose (mg/kg/day)	**Control**	**LD**	**MD**	**HD**
1st day	139.33±4.13	142.24±4.12	152.16±2.45	148.16±6.27
15 th day	173±5.79	174.12±5.26	178.16±5.79	176±5.12
30 th day	203±5.79	204.16±4.23	202.18±9.12	206.33±2.4
45 th day	236.16±9.24	239±9.24	239.23±8.28	240.25±9.24
60 th day	288.66±9.24	292.25±6.23	297.26±5.20	296.67±2.67
75 th day	319.5±8.50	320.1±9.28	326.5±4.13	324.13±4.12
90 th day	359.5±9.71	352.18±6.58	348.16±7.02	347.4±8.50

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12



Histopathology of Brain

Low Power Magnification 10X



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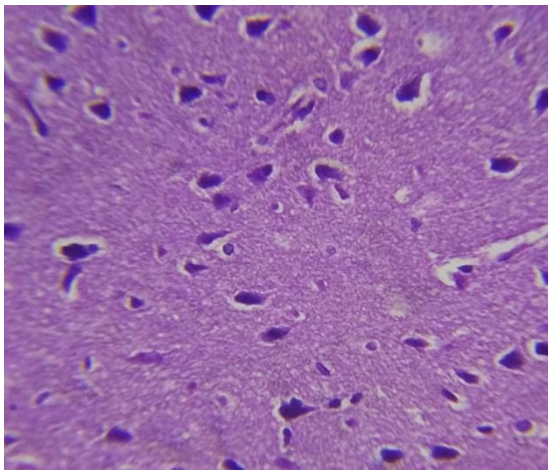
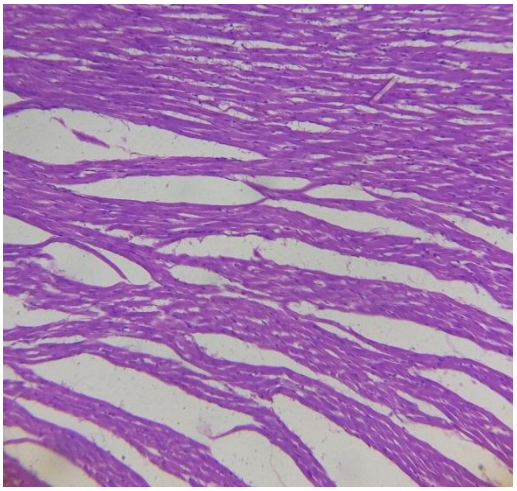


Histopathology of Heart

Low Power Magnification 10X



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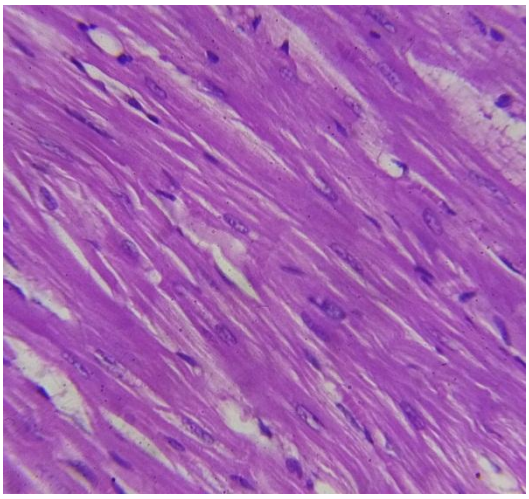
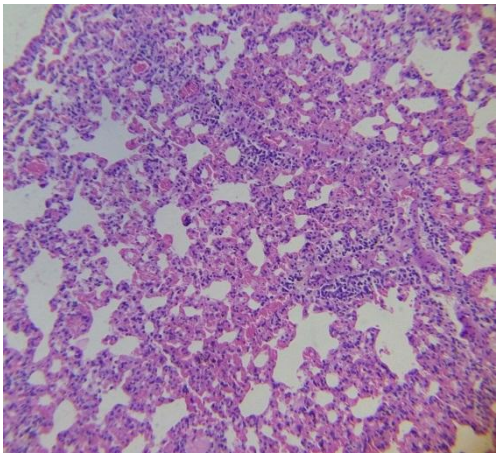


Histopathology of Lung

Low Power Magnification 10X



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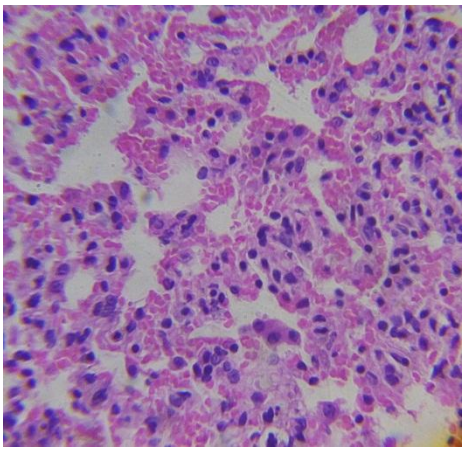
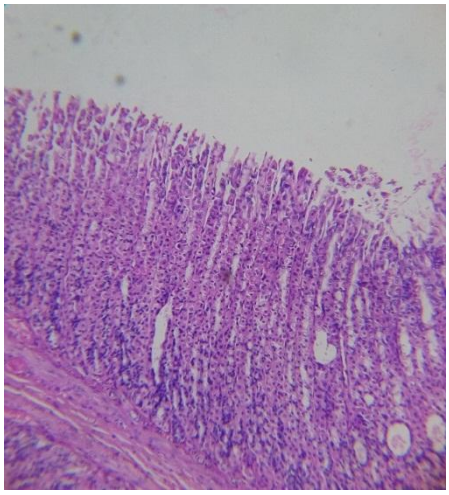


Histopathology of Stomach

Low Power Magnification 10X



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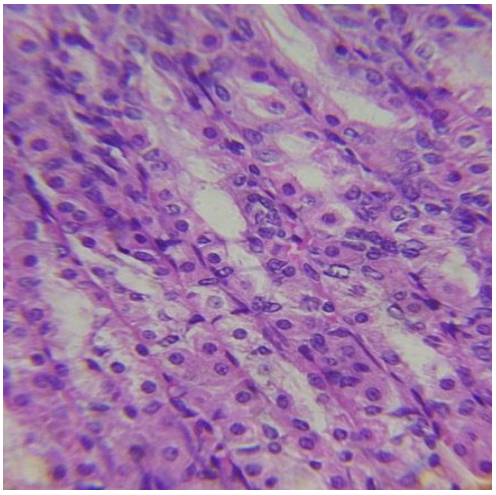

Histopathology of Liver

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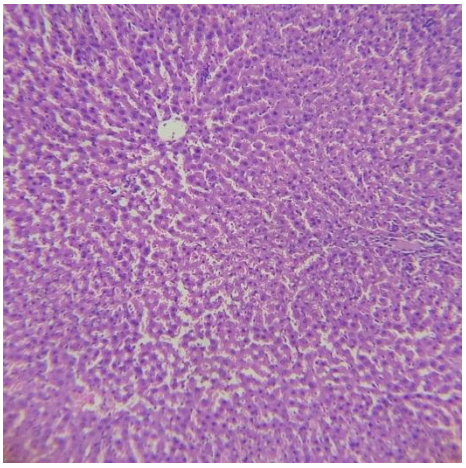

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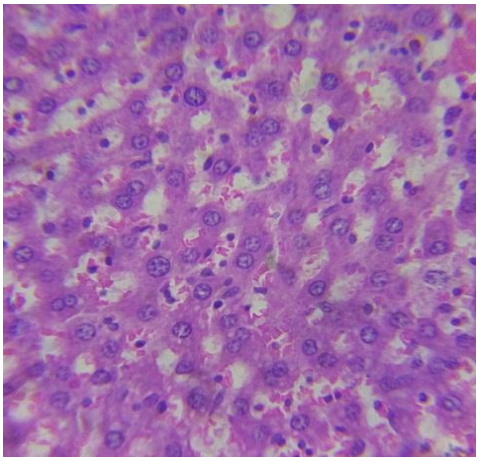
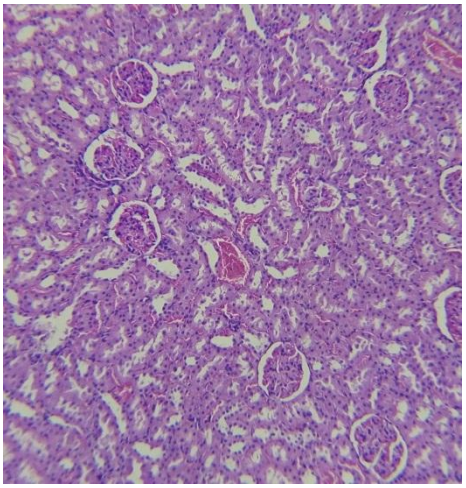


Histopathology of Kidney

Low Power Magnification 10X



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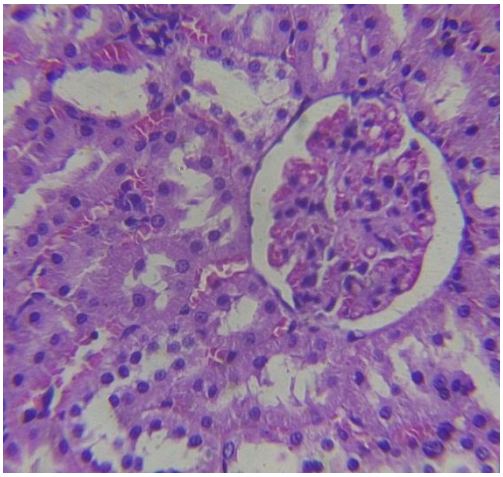
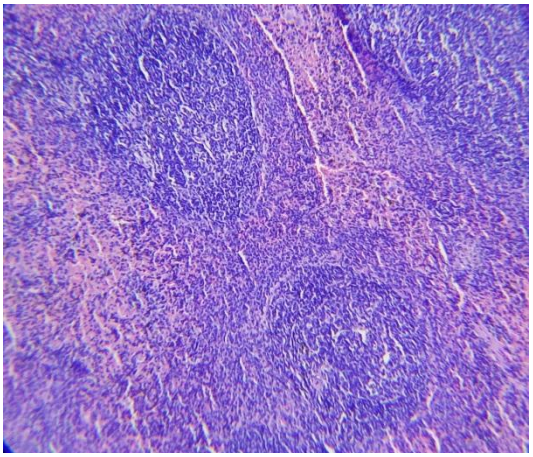


Histopathology of Spleen

Low Power Magnification 10X



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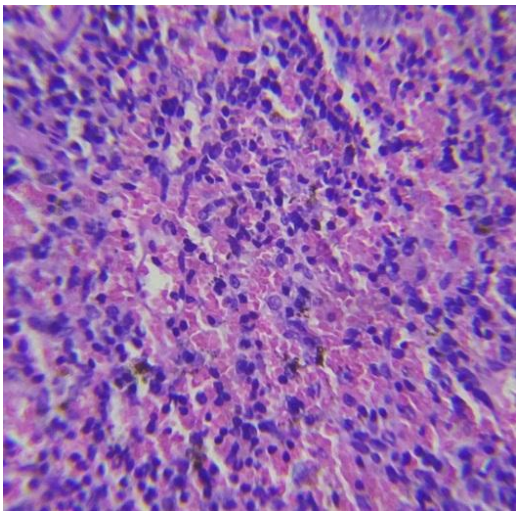
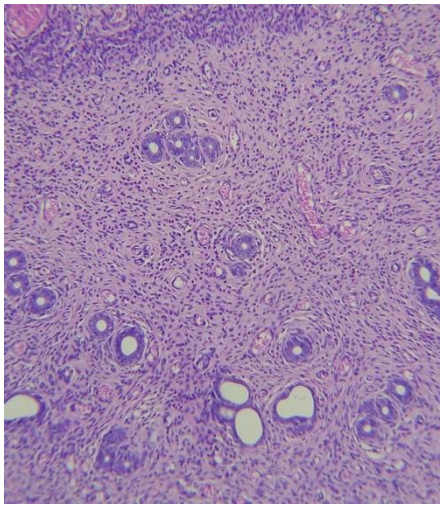


Histopathology of Uterus

Low Power Magnification 10X



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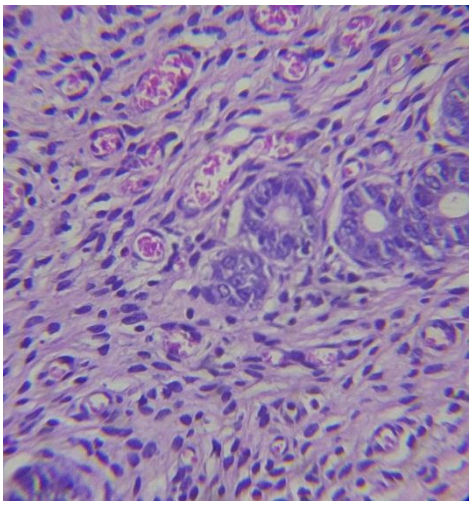
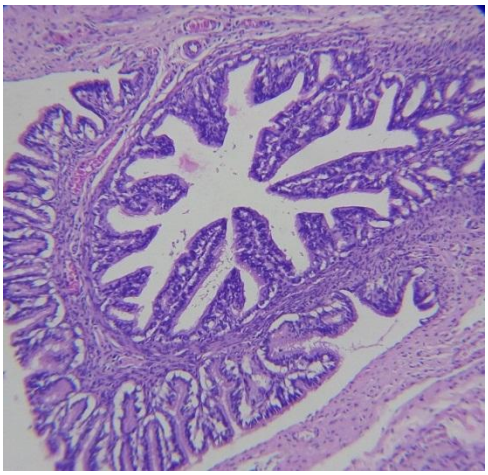


Histopathology of Ovary

Low Power Magnification 10X



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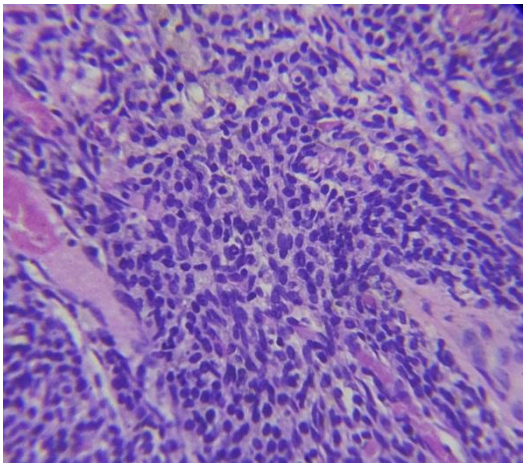


Histopathology Report

Group Id: C1HFH

Brain

- No signs of pyknosis and perineural vacuolization
- No signs of edema or degeneration were observed.
- Arrangement of neurons on cerebral cortex appears normal and dense

Heart

- Appearance of cardiomyocyte was normal with dark nuclear region. The nuclei of muscle fibers appear oval arrangement
- No evidence on accumulation of adipose tissue on interstitium
- No evidence of atherosclerosis and thrombosis

Lung

- Pneuomocyte and capillary appears normal
- Alveolar sac and septa appears normal with signs of degeneration
- Pleura and brochioles appears normal
- Pulmonary vessels and bronchioles appears normal

Stomach

- Pyloric and fundus zone of stomach appear normal
- The continuity of mucosa was normal with no evidence of ulceration

Liver

- Increased sinusoidal space with vacuolated hepatocytes were observed occasionally
- The cytoplasm of some cells shows rare empty vacuole-type spaces

Kidney

- Distinct tubular congestion were observed
- Derangement in Interstitial connective tissue was observed

Spleen

- Marginal sinus (MS) of the rat and its sinus lining cells appears normal
- Erythropoietic cells (EP) are scattered throughout the red pulp of both the samples. No abnormalities found in lymph node of both the samples

Uterus

- Appearance of endometrium, myometrium and uterine glands was normal.
- Endometrial gland, epithelium and blood vessels appears normal

Ovary

- Sequential arrangement of granulosa cells arounds oocyte was normal and regular
- Follicular cells, cytoplasm and nucleus appears normal

Histopathology Report

Group Id: C1HFH

Brain

- Brain showing intact molecular and granular layer of neuronal cells
- Arrangement of the neurons appears regular with no signs of degeneration or apoptotic changes

Lung

- Lung parenchyma appears normal with regular arrangement of alveoli and alveolar sac with no signs of lymphocyte infiltration and pulmonary fibrosis

Heart

- Perfectly -arranged myocardial fibers, clear transverse striation and normal structure were observed.
- Appearance of cardiomyocyte was normal with dark nuclear region. The nuclei of muscle fibers appear oval arrangement

Stomach

- Lamina propria appears normal with no evidence of infiltration and inflammation
- Mucosal wall appears normal with regular arrangement of connective tissue

Liver

- Hepatocyte appears with dark pigment chromatin in centri lobular and periportal region
- Hepatic sinusoid and hepatic cord was normal

Kidney

- Glomerular cell integrity, basement membrane and nephrotic bundle appears normal
- No signs of lesion or inflammation were observed
- Proximal and distal convoluted tubule appears normal

Spleen

- Marginal vascular zone radiated in between red and white pulp
- Appearance of splenic red pulp was normal

Uterus

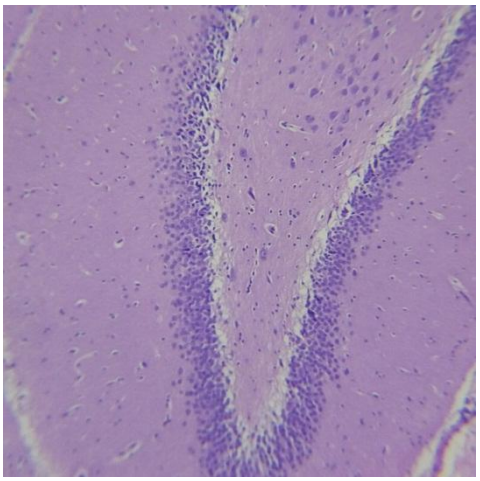
- Arrangement of stratum basale, functionale and surface epithelium seems normal
- Endometrial gland, epithelium and blood vessels appears normal

Ovary

- •Histopathological analysis of ovary showing normal corpus luteum (CL) and Primordial follicles with few mature ovarian follicles with no signs of abnormality.

Histopathology of Brain

Low Power Magnification 10X



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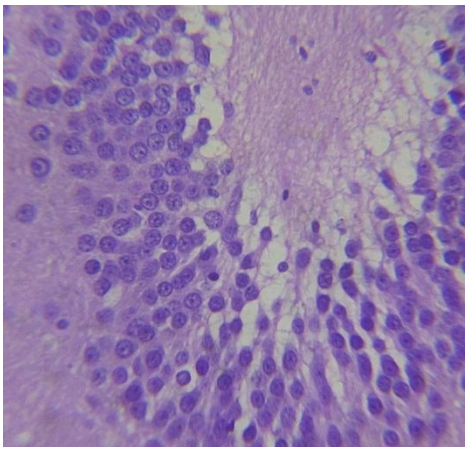
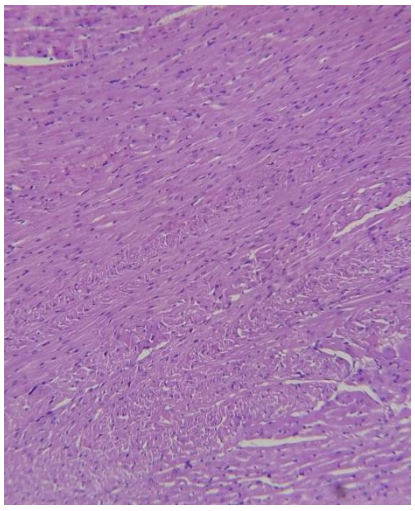


Histopathology of Heart

Low Power Magnification 10X



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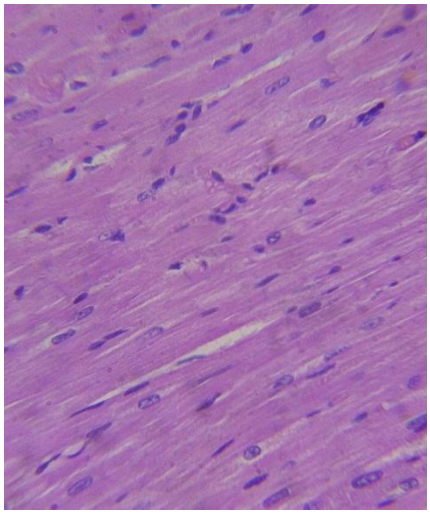
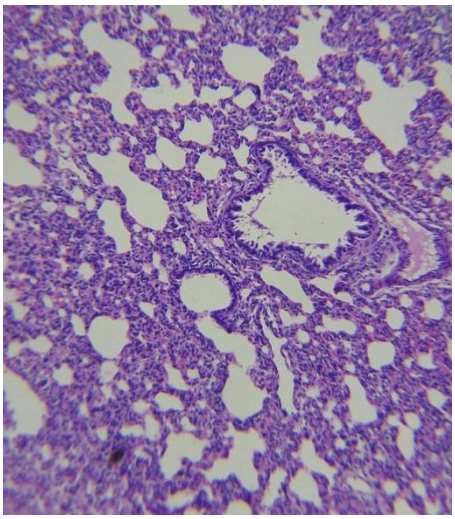


Histopathology of Lung

Low Power Magnification 10X



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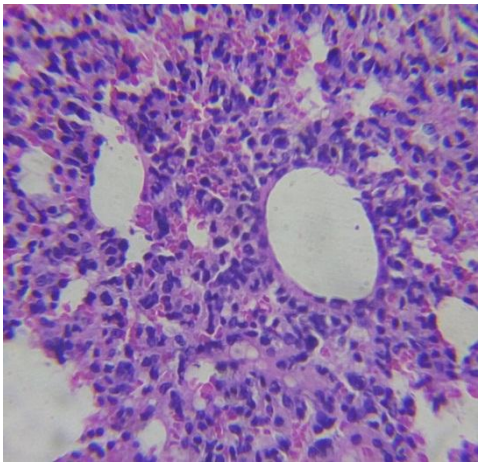
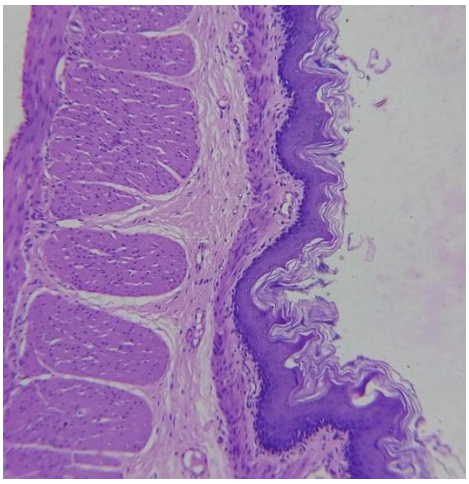


Histopathology of Stomach

Low Power Magnification 10X



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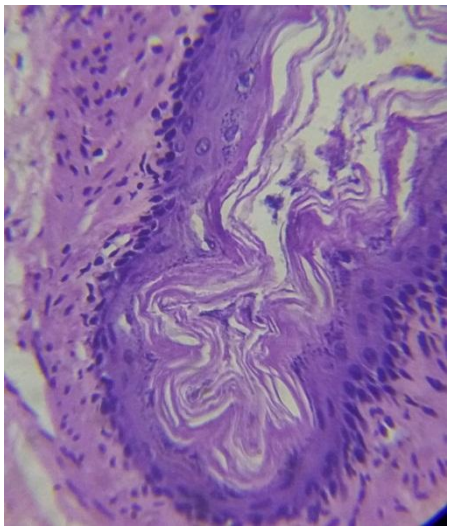
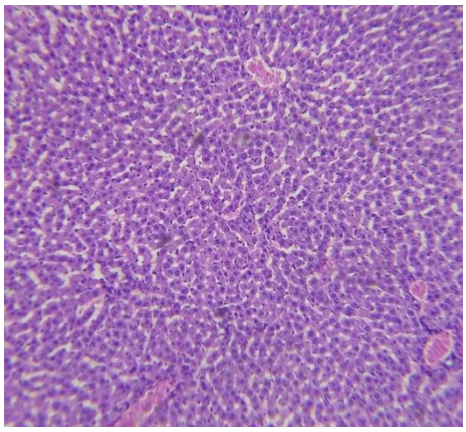


Histopathology of Liver

Low Power Magnification 10X



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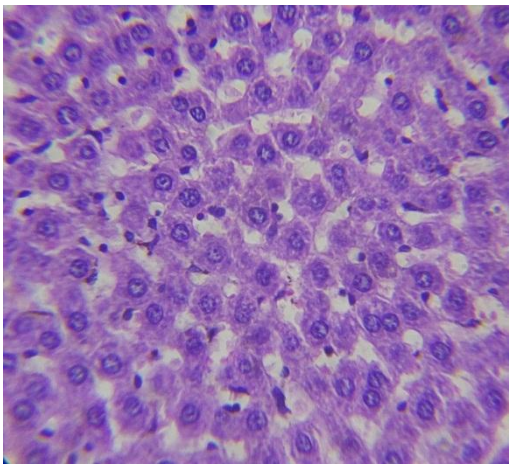
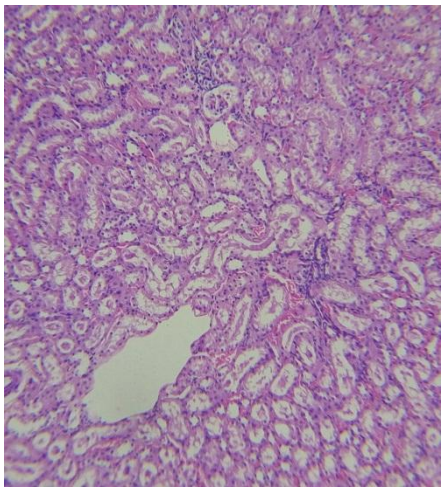


Histopathology of Kidney

Low Power Magnification 10X



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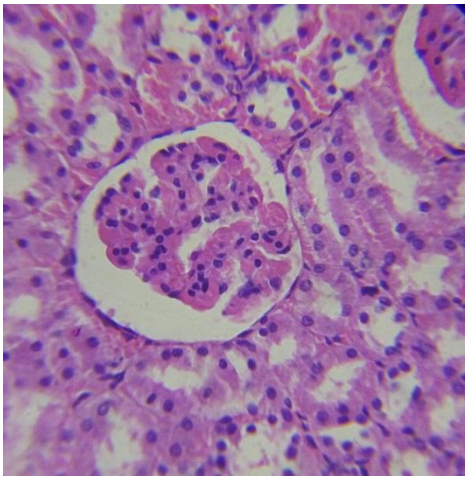
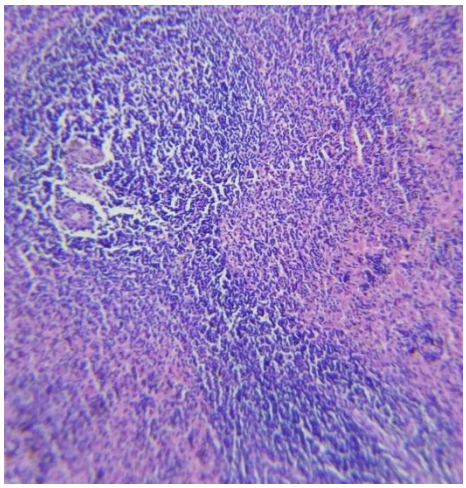


Histopathology of Spleen

Low Power Magnification 10X



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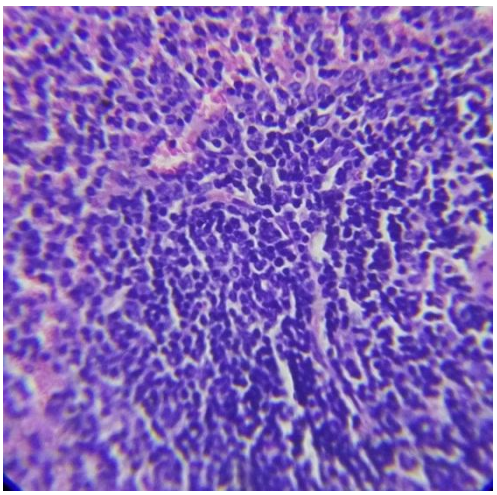
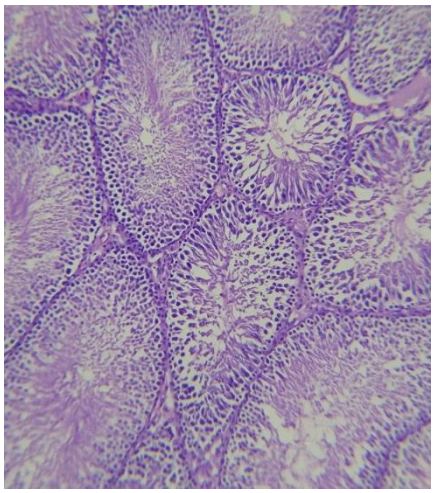


Histopathology of Testes

Low Power Magnification 10X



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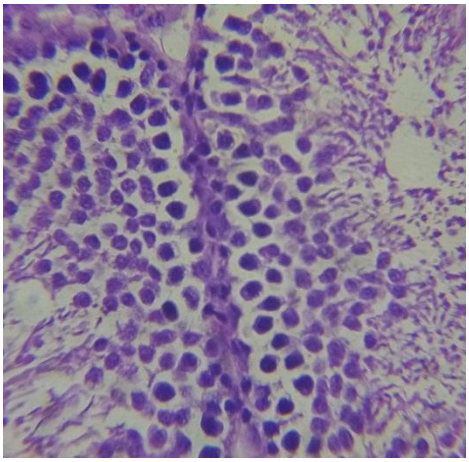


Histopathology Report

Group ID: C1HMH

Brain

- Primary dendrites and glial cells appears normal
- The CA zones of brain are filles with densely packed Pyramidal cells

Heart

  - No evidence on accumulation of adipose tissue on interstitium
  - No evidence of atherosclerosis and thrombosis

Lung

- No signs of airway secretion and bronchial secretion
- Bronchial blood vessels and connective tissue appears normal with no sings of pulmonary edema

Stomach

- No signs of ulcer and glandular degeneration were observed
- Appearance of Sub-mucosa and gastric glands appear normal

Liver

- Appearance of portal vein was normal
- Appearance of hepatic cord was normal and radial in nature, no signs of cellular degeneration

Kidney

- Glomeruli appears hypertrophic
- No signs of lesion or inflammation were observed
- Proximal and distal convoluted tubule appears normal

Spleen

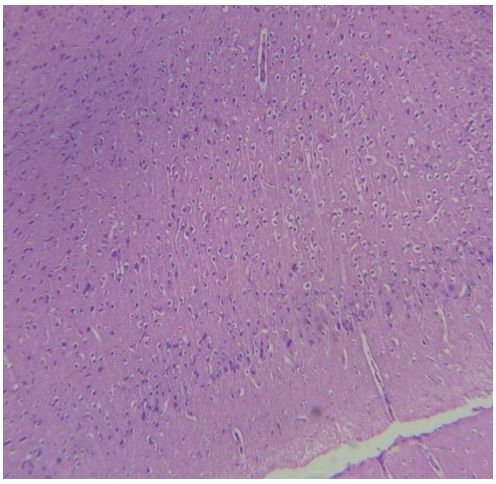
- No signs of perivascular inflammation
- Appearance of splenic sinuses, Splenic cord and endothelial orientation was normal

TESTES

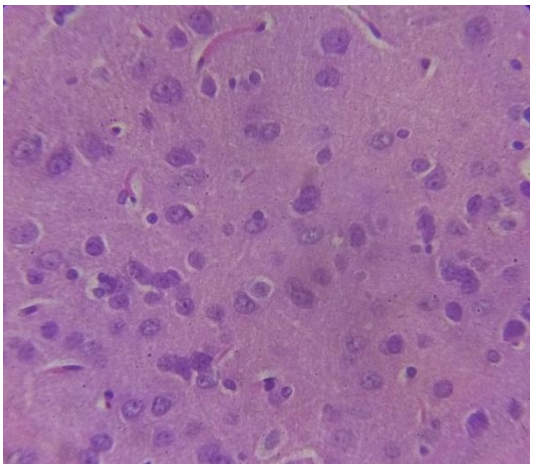
- Appearance of leydig cells, interstitial tissue , seminiferous tubule, Sertoli cells and spermatogonia were normal
- No signs of interstitial fibrosis were observed
- Sperm oriented towards the center of sertoli cells with cluster of tail projected outside was observed

Histopathology of Brain

Low Power Magnification 10X

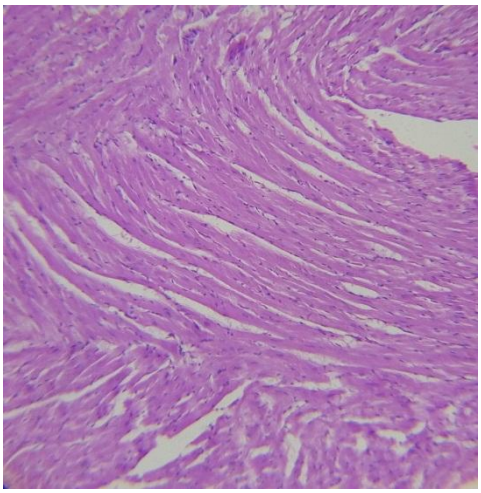


High Power Magnification 40X



Histopathology of Heart

Low Power Magnification 10X



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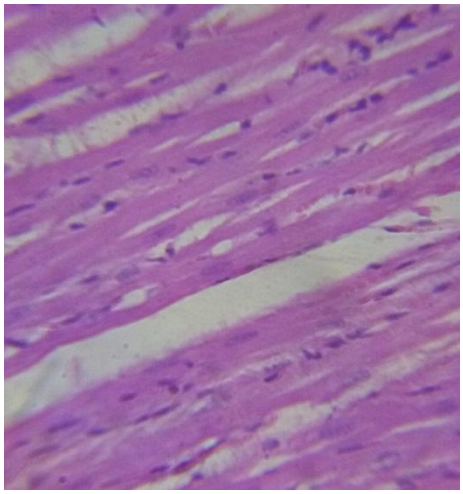
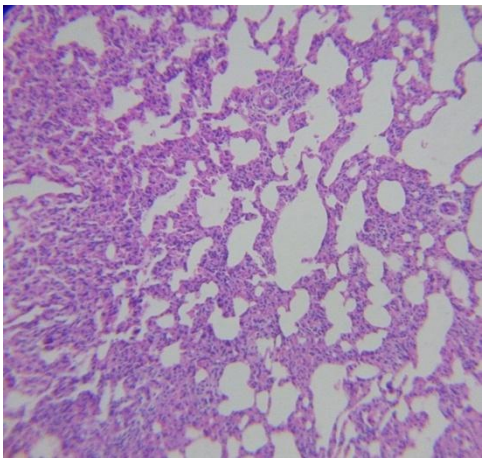


Histopathology of Lung

Low Power Magnification 10X



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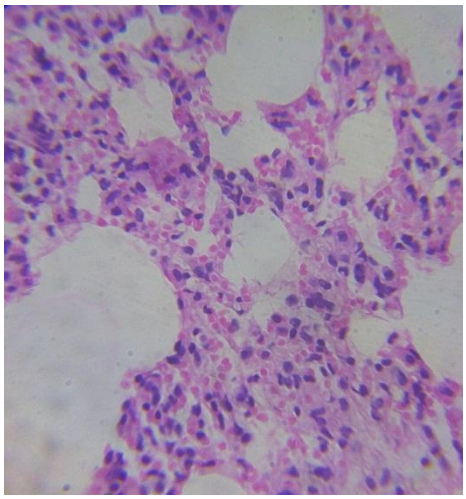
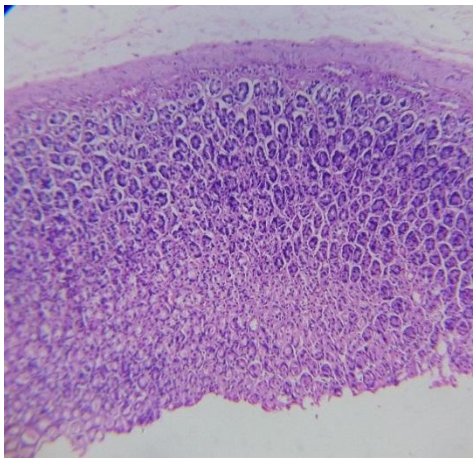


Histopathology of Stomach

Low Power Magnification 10X



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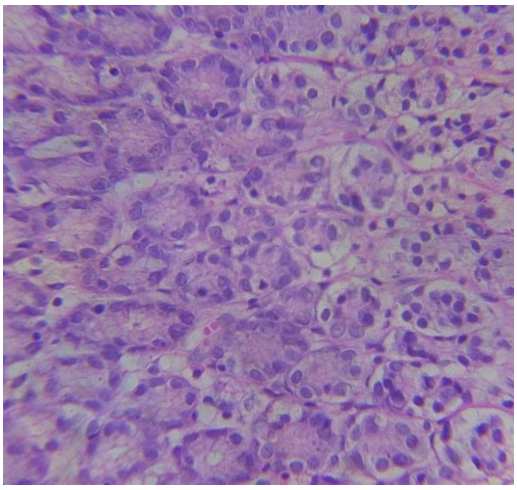
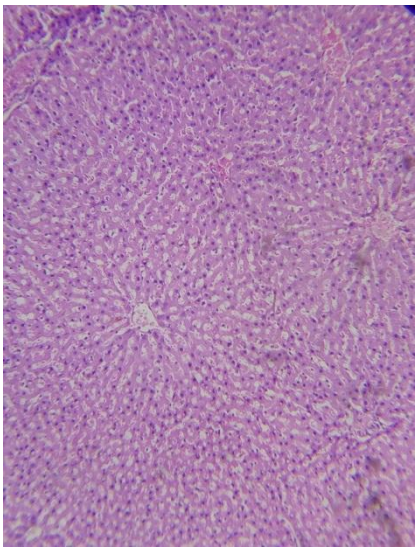


Histopathology of Liver

Low Power Magnification 10X



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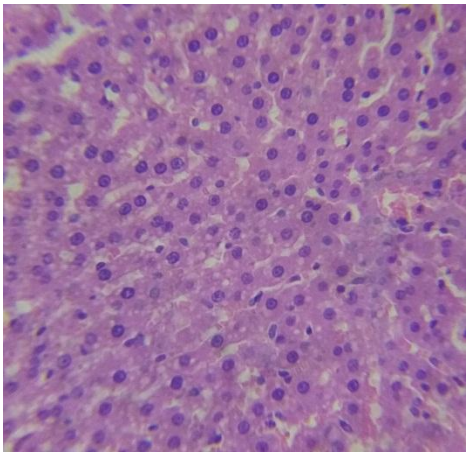
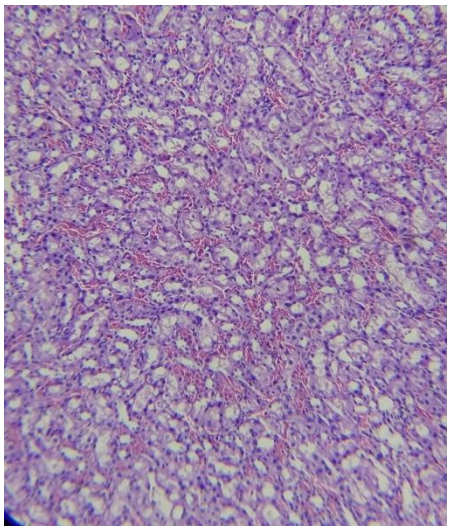


Histopathology of Kidney

Low Power Magnification 10X



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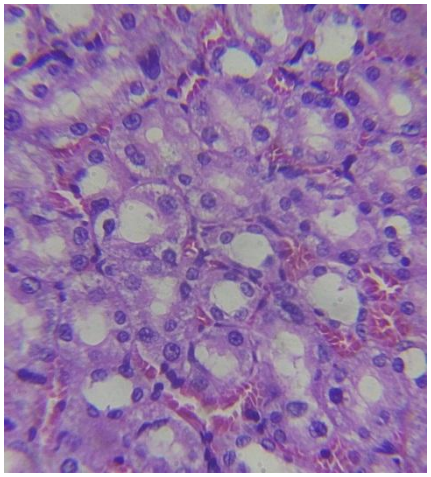
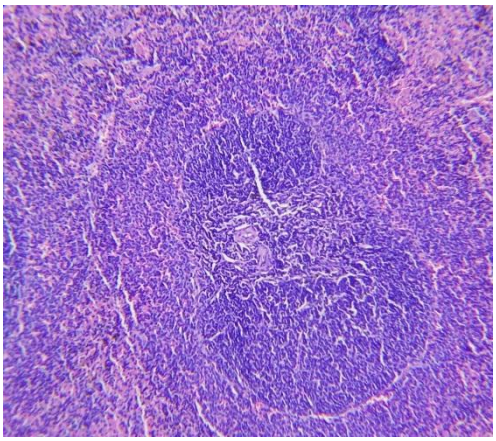


Histopathology of Spleen

Low Power Magnification 10X



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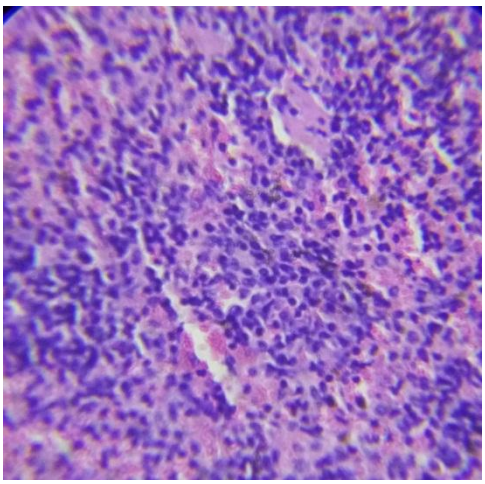
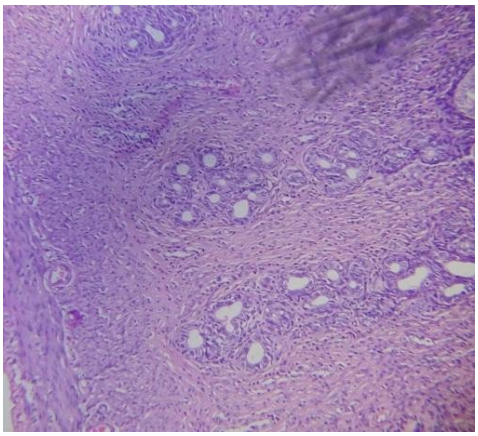


Histopathology of Uterus

Low Power Magnification 10X



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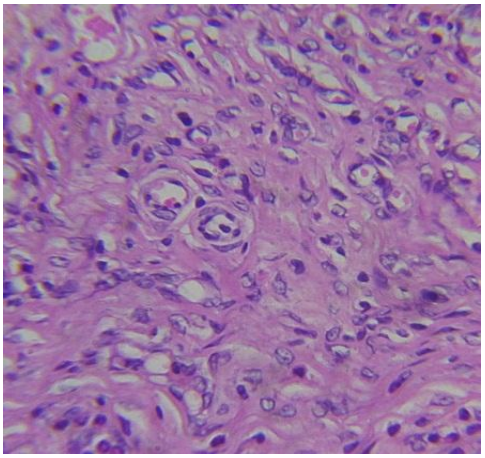
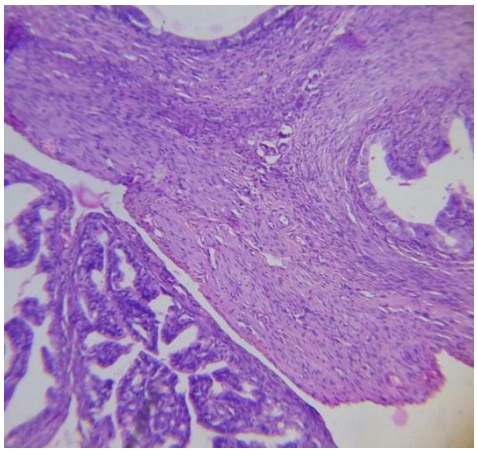


Histopathology of Ovary

Low Power Magnification 10X



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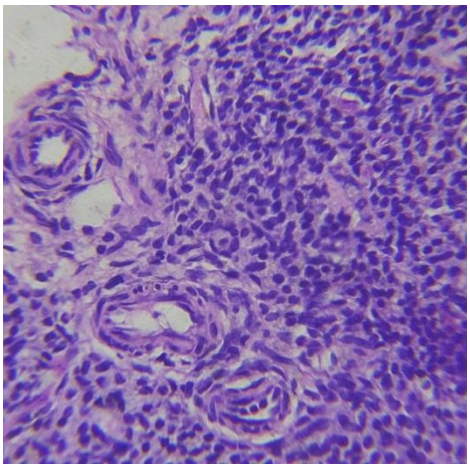


Histopathology Report

Group Id: C1LFH

Brain

- No signs of pyknosis and perineural vacuolization
- No signs of edema or degeneration were observed.
- Arrangement of neurons on cerebral cortex appears normal and dense

Heart

- Appearance of cardiomyocyte was normal with dark nuclear region. The nuclei of muscle fibers appear oval arrangement
- No evidence on accumulation of adipose tissue on interstitium
- No evidence of atherosclerosis and thrombosis

Lung

- Pneuomocyte and capillary appears normal
- Alveolar sac and septa appears normal with signs of degeneration
- Pleura and brochioles appears normal
- Pulmonary vessels and bronchioles appears normal

Stomach

- Pyloric and fundus zone of stomach appear normal
- The continuity of mucosa was normal with no evidence of ulceration

Liver

- Increased sinusoidal space with vacuolated hepatocytes were observed occasionally
- The cytoplasm of some cells shows rare empty vacuole-type spaces

Kidney

- Distinct tubular congestion were observed
- Derangement in Interstitial connective tissue was observed

Spleen

- Marginal sinus (MS) of the rat and its sinus lining cells appears normal
- Erythropoietic cells (EP) are scattered throughout the red pulp of both the samples. No abnormalities found in lymph node of both the samples

Uterus

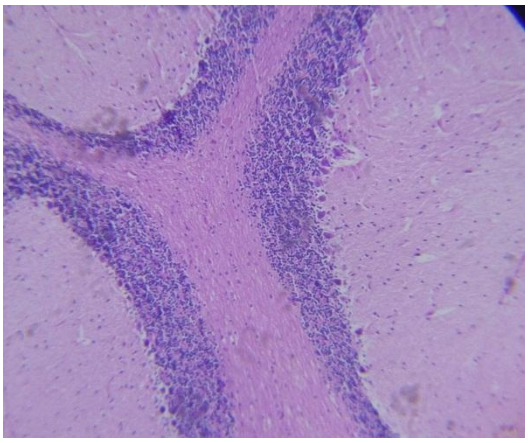
- Appearance of endometrium, myometrium and uterine glands was normal.
- Endometrial gland, epithelium and blood vessels appears normal

Ovary

- Sequential arrangement of granulosa cells arounds oocyte was normal and regular
- Follicular cells, cytoplasm and nucleus appears normal

Histopathology of Brain

Low Power Magnification 10X



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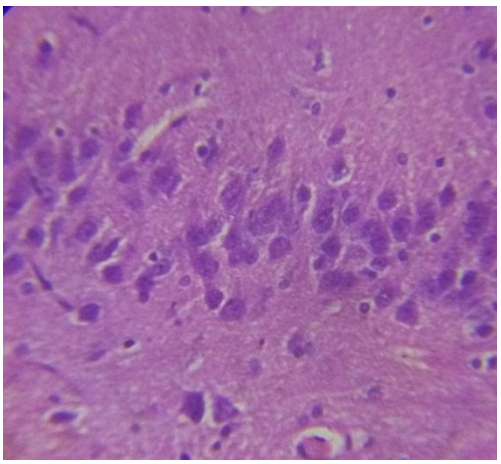
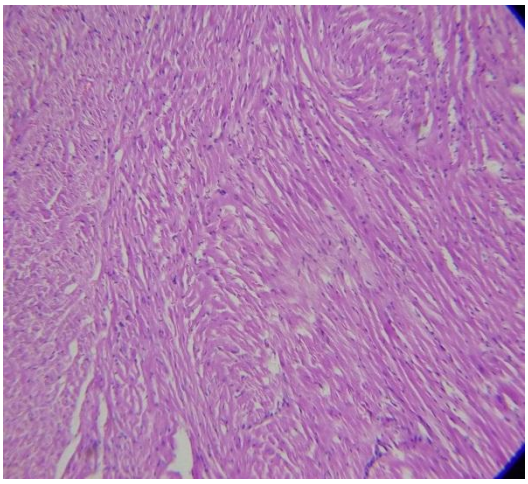


Histopathology of Heart

Low Power Magnification 10X



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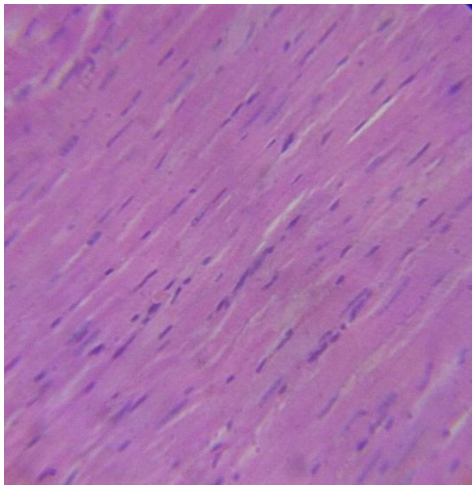
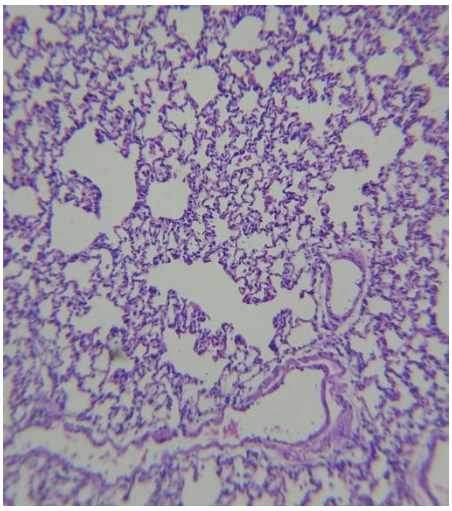


Histopathology of Lung

Low Power Magnification 10X



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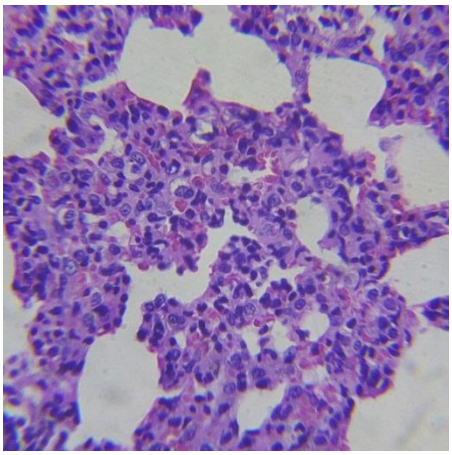
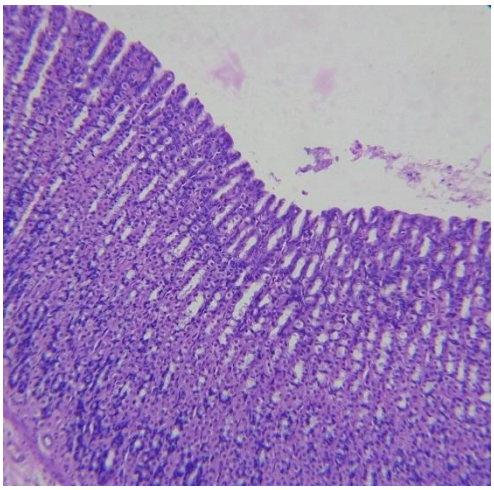


Histopathology of Stomach

Low Power Magnification 10X



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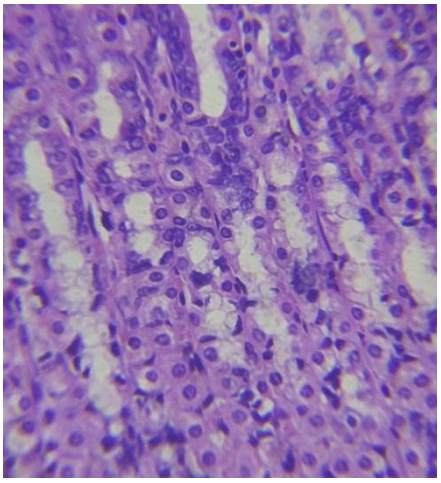
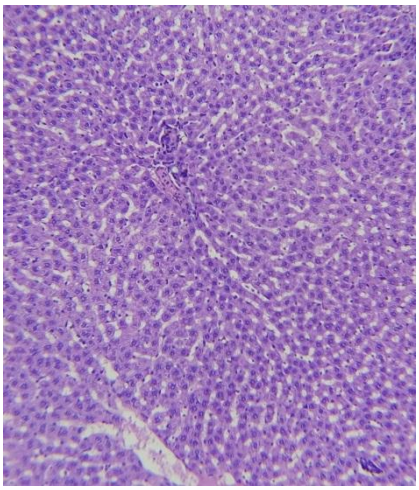


Histopathology of Liver

Low Power Magnification 10X



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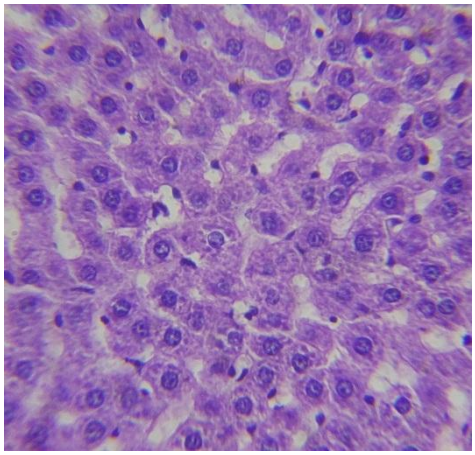
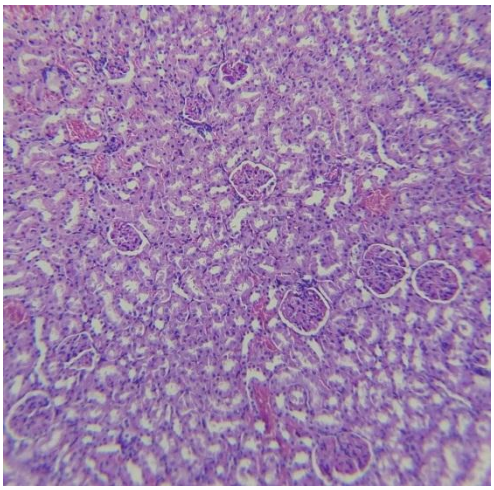


Histopathology of Kidney

Low Power Magnification 10X



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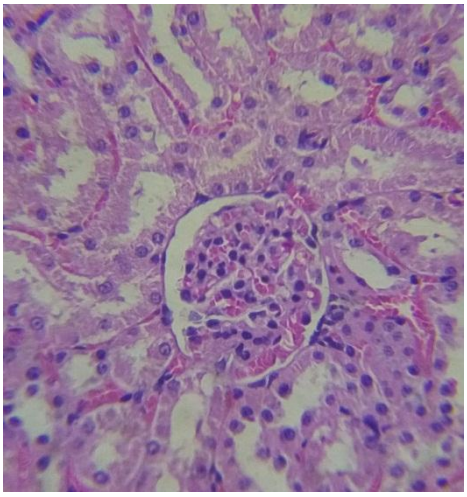
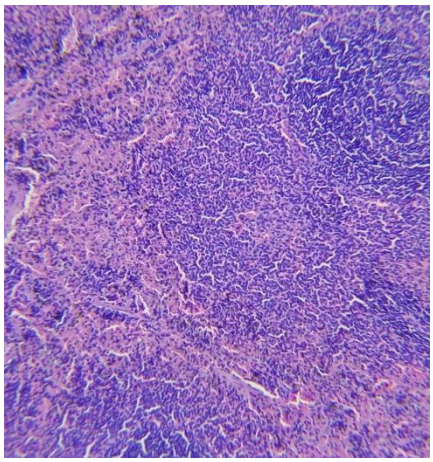


Histopathology of Spleen

Low Power Magnification 10X



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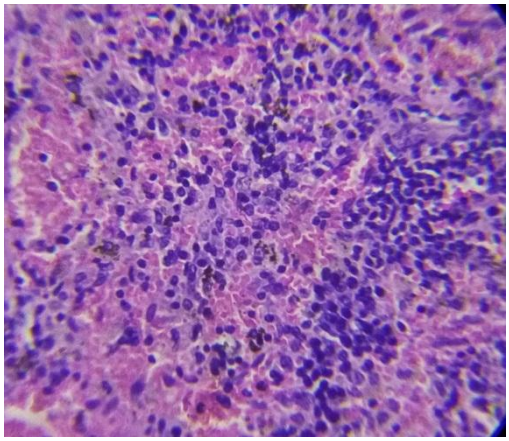
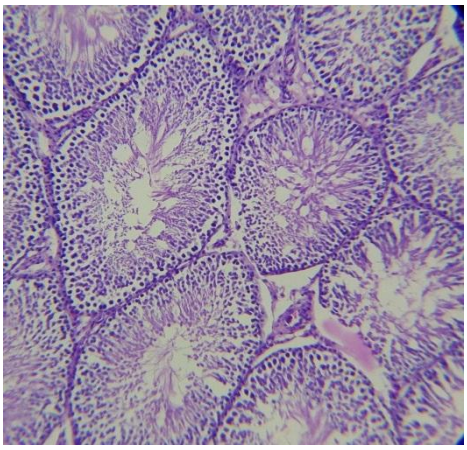


Histopathology of Testes

Low Power Magnification 10X



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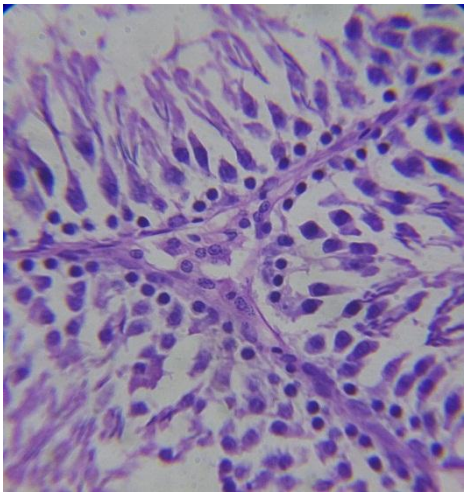


Histopathology Report

Group ID: C1LMH

Brain

- Primary dendrites and glial cells appears normal
- The CA zones of brain are filles with densely packed Pyramidal cells

Heart

  - Appearance of cardiomyocyte was normal with dark nuclear region. The nuclei of muscle fibers appear oval arrangement

Lung

- No signs of airway secretion and bronchial secretion
- Bronchial blood vessels and connective tissue appears normal with no sings of pulmonary edema

Stomach

- Lumina of blood vessels appears normal. Appearance of glandular lumen was normal
- Intracytoplasmic zone of mucosa appears normal

Spleen

- Appearance of LF – lymphoid follicle; PALS – periarterial lymphoid sheath was normal with no significant signs of enlargement
- No signs of immunological activities

Liver

- Liver parenchyma appears normal with no evidence of necrosis
- Appearance of terminal hepatic venules (central veins) to the portal tracts was normal

Kidney

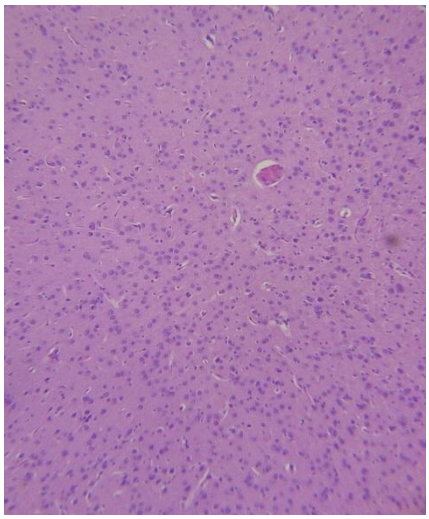
- Some renal tubules and glomeruli appears hypertrophic
- Interstitial connective tissue appears cohesive with distinct space in between
- Proximal and distal convoluted tubule appears normal

TESTES

- Normal sertoli cell aligned properly on the basement membrane with oval dome shaped nucleus shows the normal morphology of the seminiferous tubule were observed
- Appearance of leydig cells, interstitial tissue , seminiferous tubule, Sertoli cells and spermatogonia were normal

Histopathology of Brain

Low Power Magnification 10X



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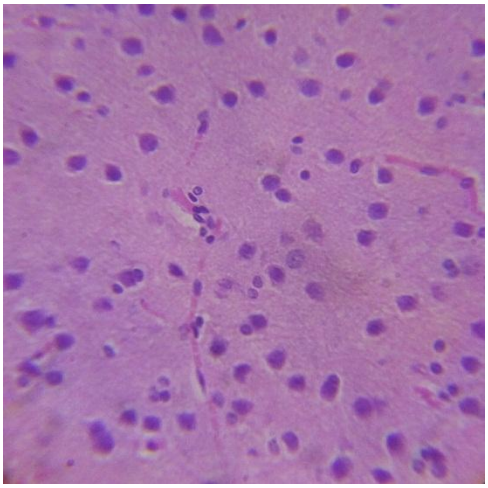
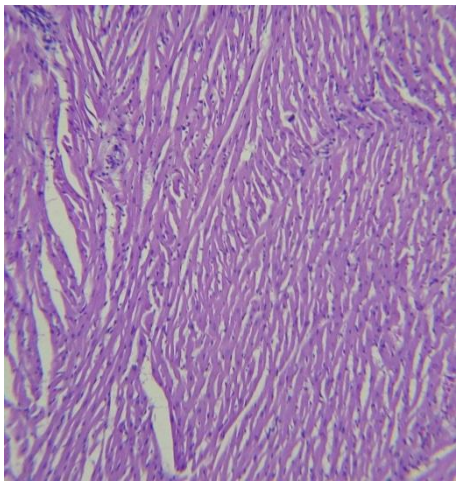


Histopathology of Heart

Low Power Magnification 10X



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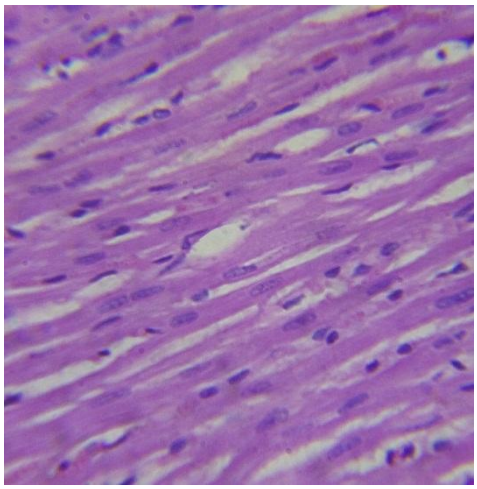
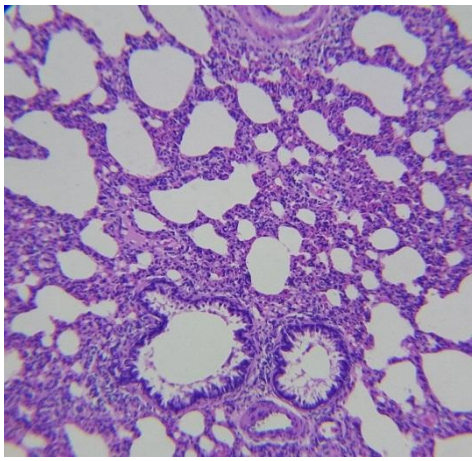


Histopathology of Lung

Low Power Magnification 10X



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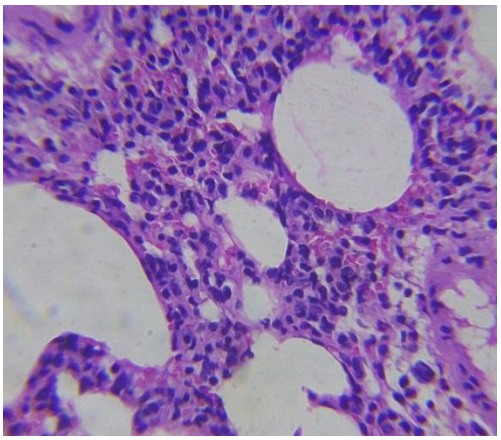
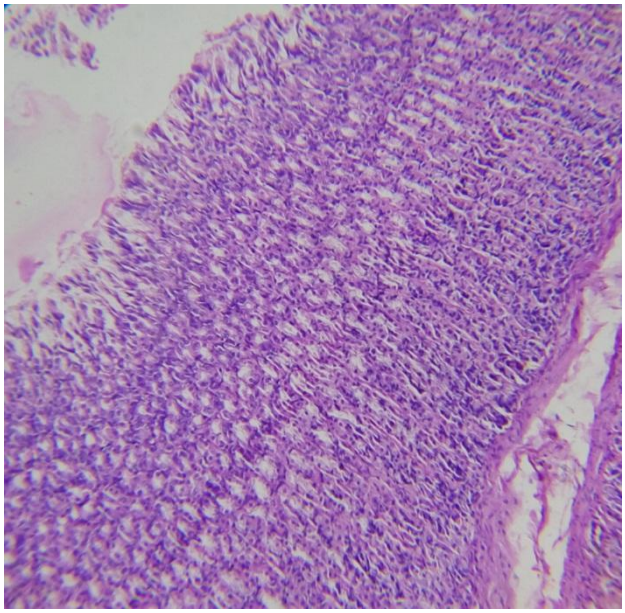


Histopathology of Stomach

Low Power Magnification 10X



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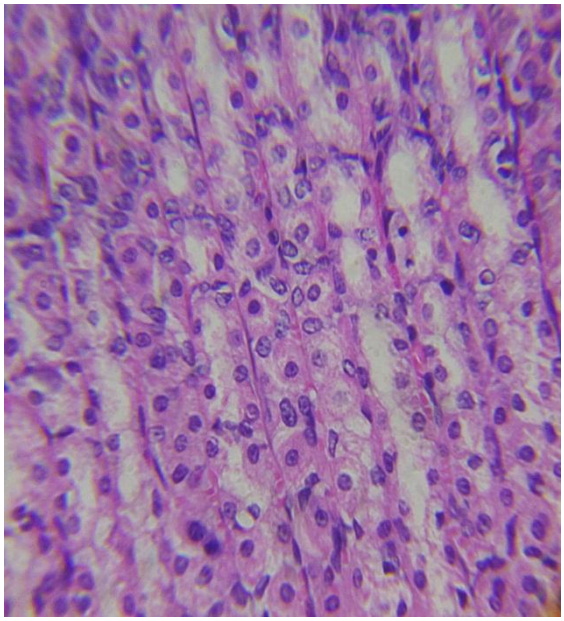
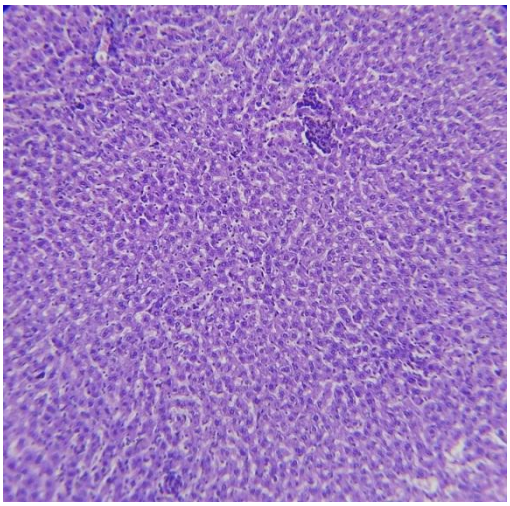


Histopathology of Liver

Low Power Magnification 10X



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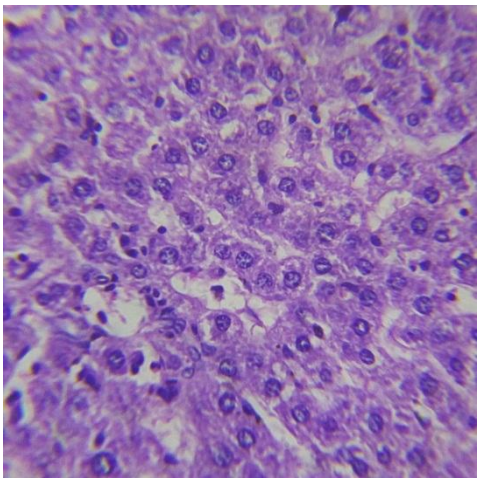
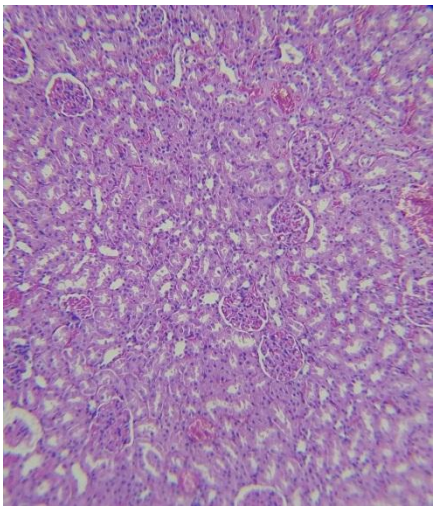
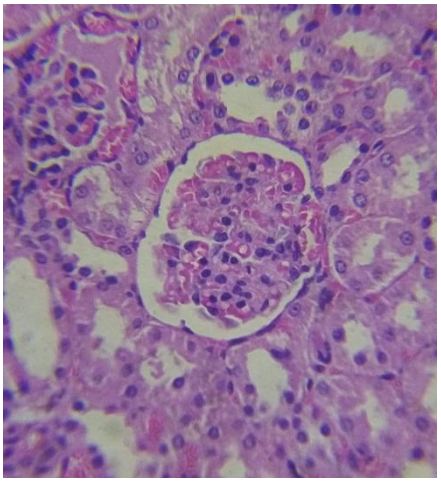


Histopathology of Kidney

Low Power Magnification 10X

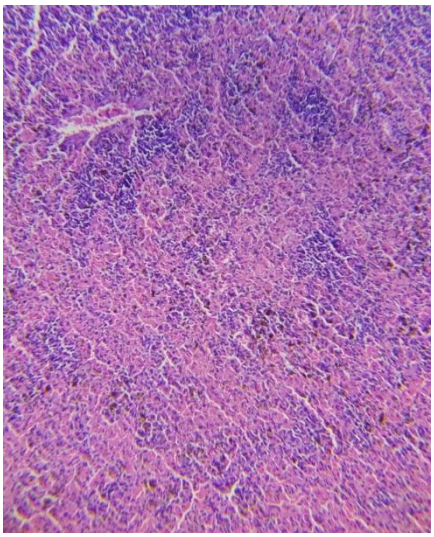


High Power Magnification 40X



Histopathology of Spleen

Low Power Magnification 10X



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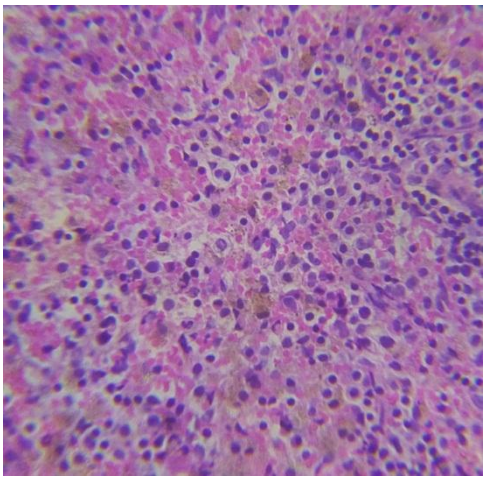
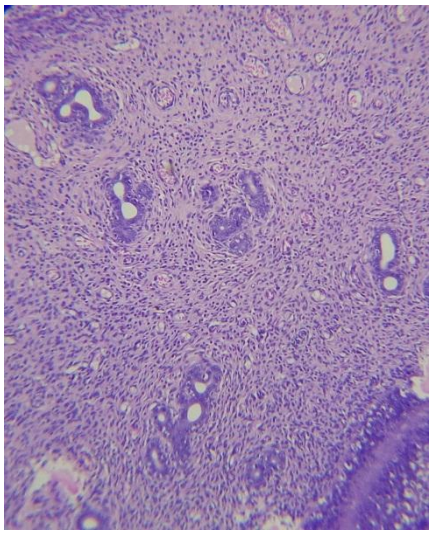


Histopathology of Uterus

Low Power Magnification 10X



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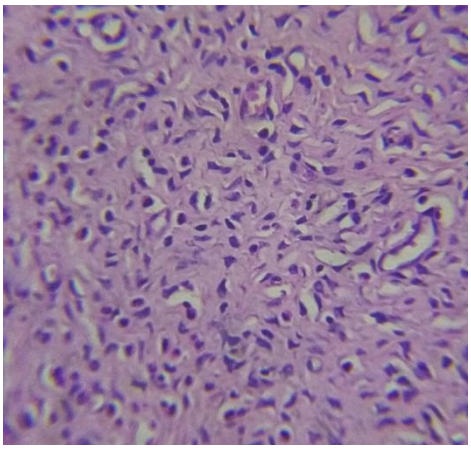
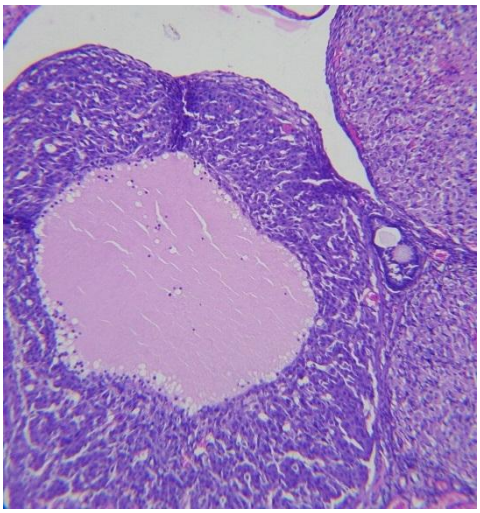
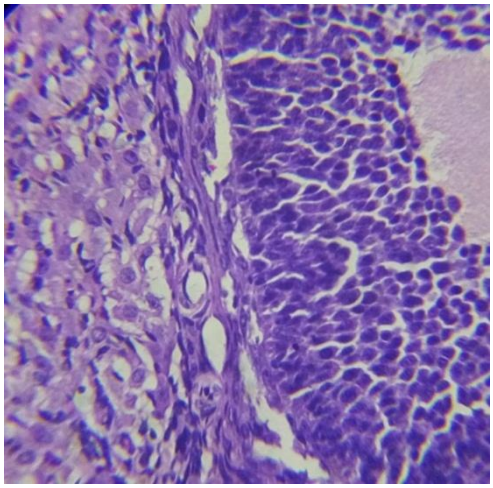


Histopathology of Ovary

Low Power Magnification 10X



High Power Magnification 40X



Histopathology Report

Group ID: C1MFH

Brain

- Appearance of Hippocampal neurons was normal with dense network
- No signs of ischemic changes in the cerebral hemisphere

Heart

- No evidence of necrotic myocardium
- Appearance of fibrils and cross striations are equidistant

Lung

- Perivascular region appears normal, Alveolar septa and wall appeared widen and normal
- No signs of lymphocyte cuffing

Stomach

- Lumina of blood vessels appears normal. Appearance of glandular lumen was normal
- Intracytoplasmic zone of mucosa appears normal

Spleen

- No signs of perivascular inflammation
- Appearance of splenic sinuses, Splenic cord and endothelial orientation was normal

Liver

- Appearance of terminal hepatic venules (central veins) to the portal tracts was normal
- No signs of nodular degeneration and cirrhosis .
- No evidence of collagen (fibrosis)

Kidney

- Interstitial connective tissue appears cohesive with distinct space in between
- Proximal and distal convoluted tubule appears normal

Ovary

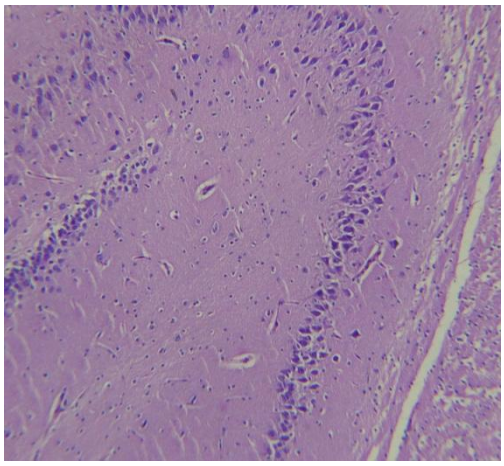
- Appearance of antral follicle, primary oocyte and secondary follicles are normal

Uterus

- Arrangement of stratum basale, functionale and surface epithelium seems normal
- Endometrial gland, epithelium and blood vessels appears normal

Histopathology of Brain in Sub-acute toxicity Study

Low Power Magnification 10X



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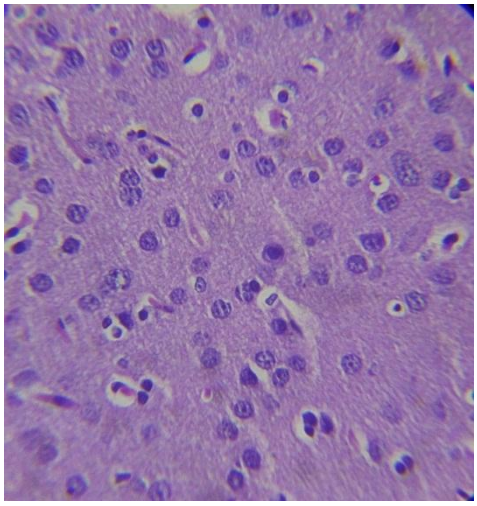
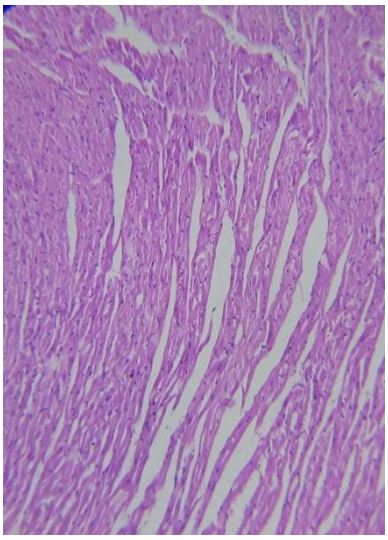


Histopathology of Heart in Sub-acute toxicity Study

Low Power Magnification 10X



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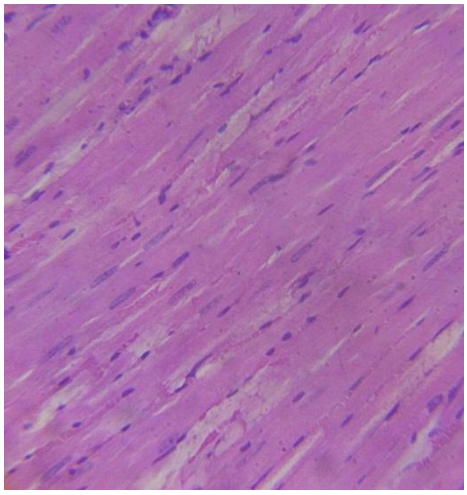

Histopathology of Lung in Sub-acute toxicity Study

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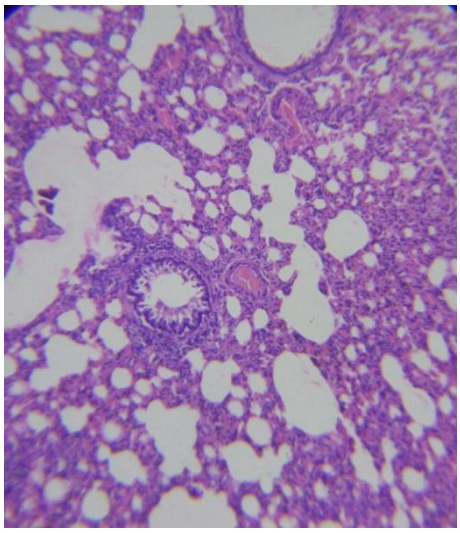

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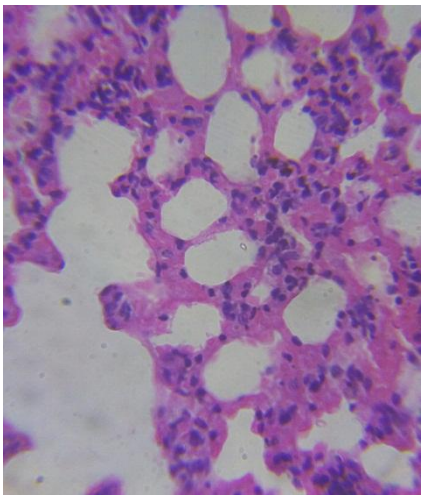

Histopathology of Stomach in Sub-acute toxicity Study

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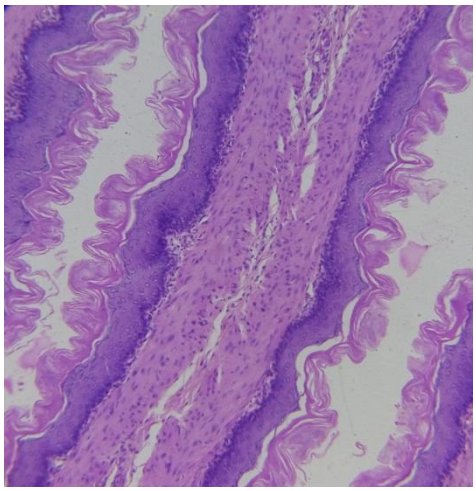

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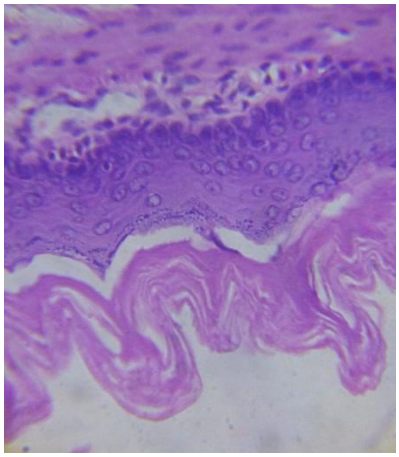

Histopathology of Liver in Sub-acute toxicity Study

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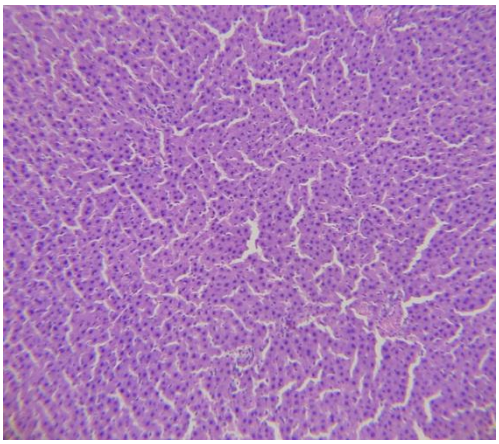

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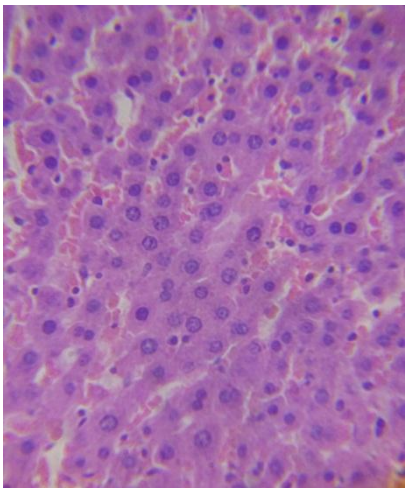

Histopathology of Kidney in Sub-acute toxicity Study

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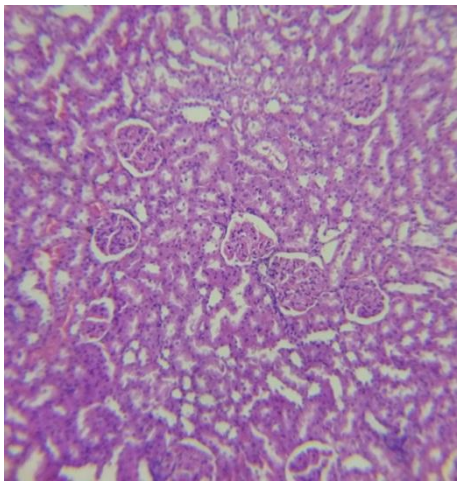

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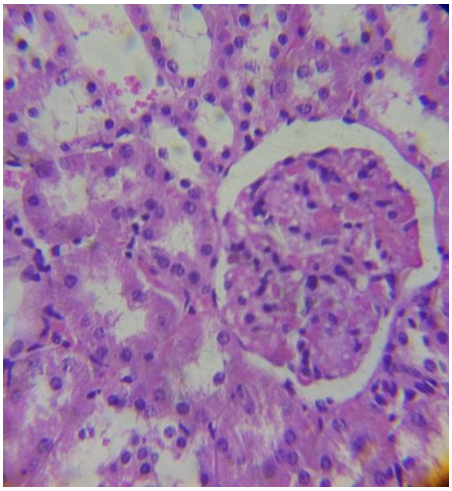

Histopathology of Spleen in Sub-acute toxicity Study

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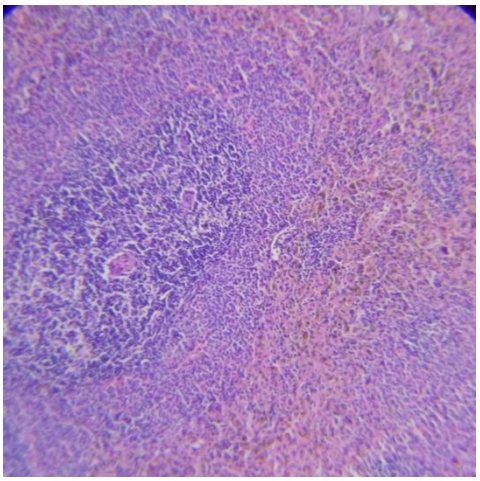

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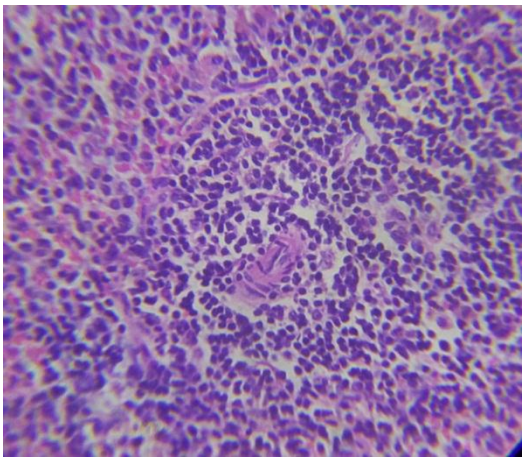
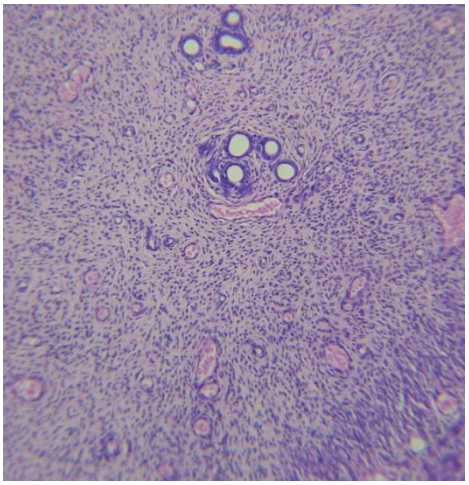


Histopathology of Uterus in Sub-acute toxicity Study

Low Power Magnification 10X



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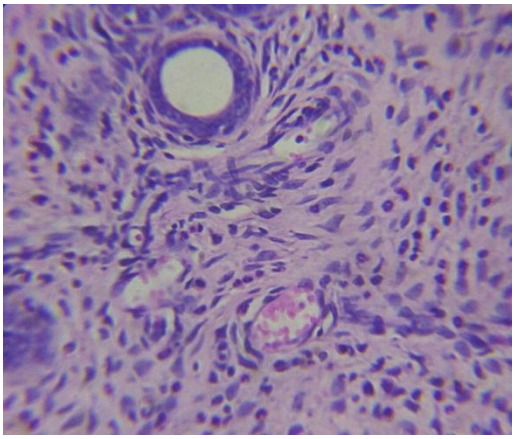
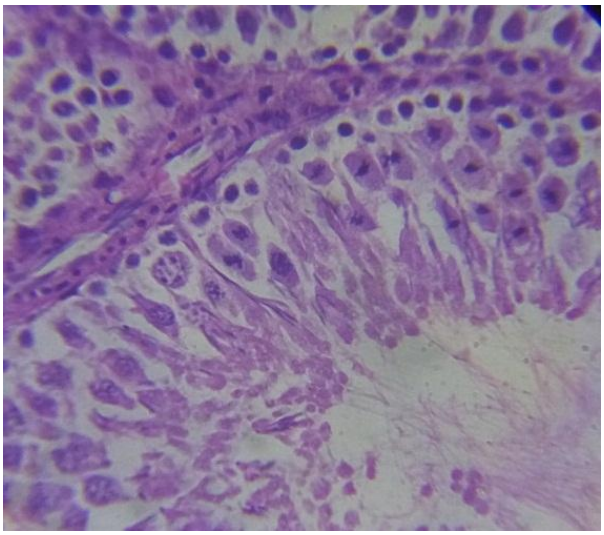


Histopathology of Testes in Sub-acute toxicity Study

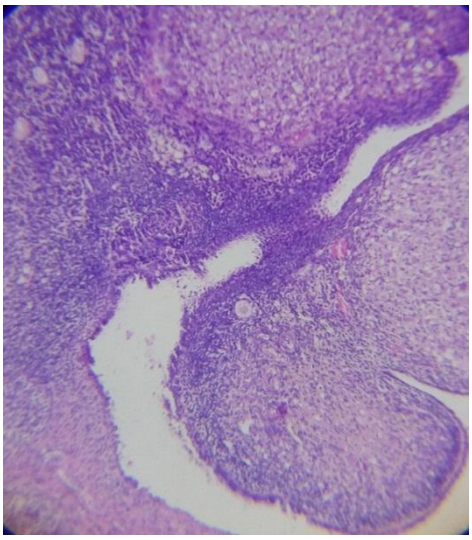
Low Power Magnification 10X

High Power Magnification 40X



Histopathology of Ovary in Sub-acute toxicity Study

Low Power Magnification 10X



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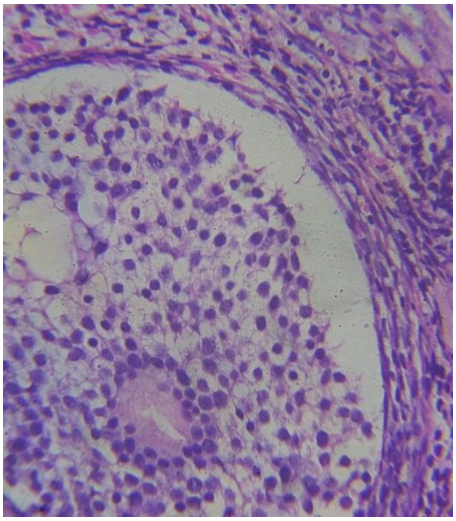


Histopathology Report

Group ID: C1MMH

Brain

- Arrangement of the neurons appears intact with no sings of degeneration or apoptotic changes in both the samples
- Cortex region showed normal neurons with polygonal to round cell bodies containing dense cytoplasm.

Heart

- No evidence of collagen deposition in myocardium.
- Appearance of myocyte was normal

Lung

- Lung parenchyma appears normal with regular arrangement of alveoli and alveolar sac with no signs of lymphocyte infiltration and pulmonary fibrosis

Stomach

- Regular arrangement of muscularisexterna and outer longitudinal muscle were observed
- Regular histology of Inner circular muscle (ICM), gastric pit (GP), and muscularis mucosae (MM) were observed

Spleen

- Marginal sinus (MS) of the rat and its sinus lining cells appears normal
- Presence of marginal at the interface of the red pulp with the PALS and follicles was observed

Liver

- Increased Sinusoidal space were observed
- Cytoplasm appears normal with widen portal tract
- The centrilobular hepatocytes appears normal with occasional cytoplasmic vacuolization
- No evidence of mesenchymal reaction on to the hepatic parenchyma

Kidney

- Derangement in Interstitial connective tissue was observed
- Alteration in thickness of proximal convoluted tubule
- Mild tubular degeneration with increase bowman’s space

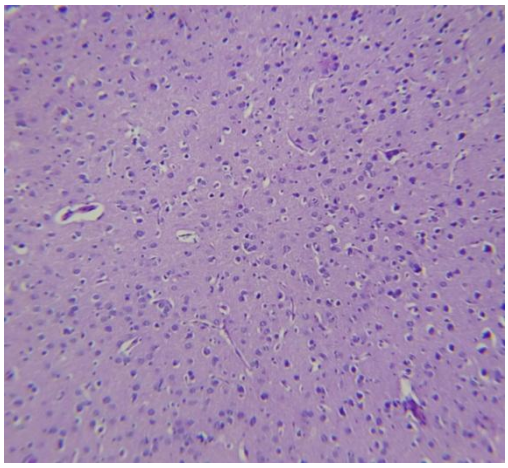
- Renal tubule with mild swollen epithelial cell
- No signs of cellular necrosis

TESTES

- Normal sertoli cell aligned properly on the basement membrane with oval dome shaped nucleus shows the normal morphology of the seminiferous tubule were observed
- Appearance of leydig cells, interstitial tissue , seminiferous tubule, Sertoli cells and spermatogonia were normal

Histopathology of Brain in Sub-acute toxicity Study

Low Power Magnification 10X



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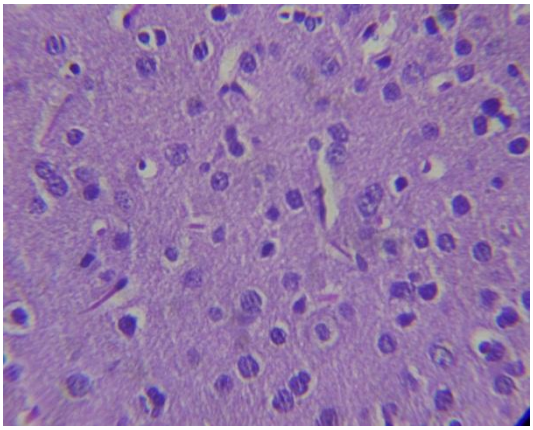

Histopathology of Heart in Sub-acute toxicity Study

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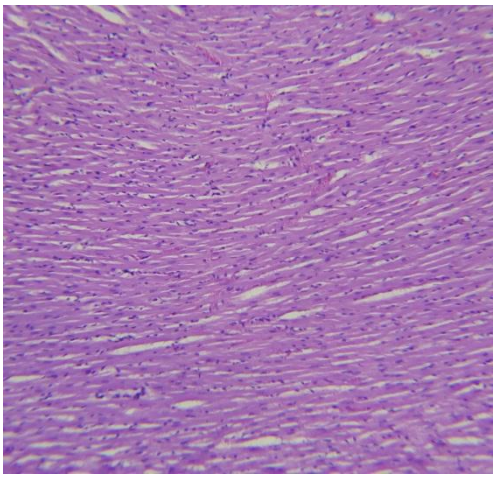

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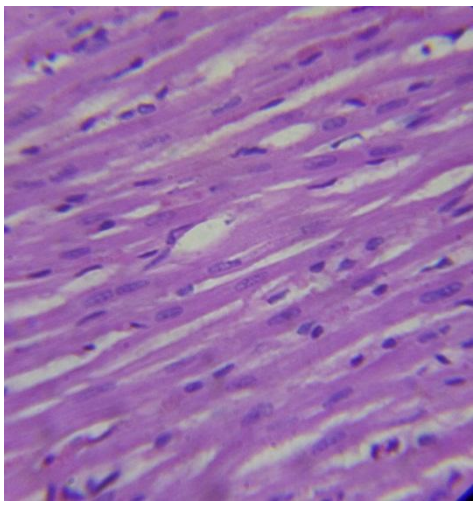

Histopathology of Lung in Sub-acute toxicity Study

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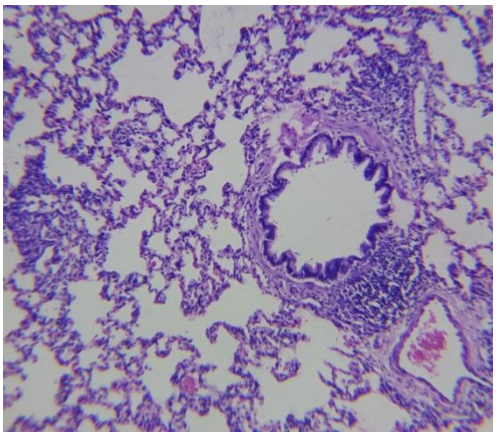

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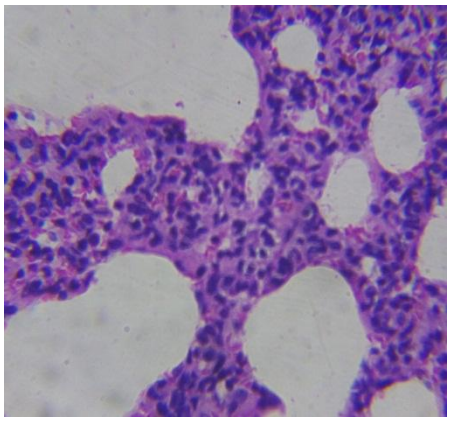

Histopathology of Stomach in Sub-acute toxicity Study

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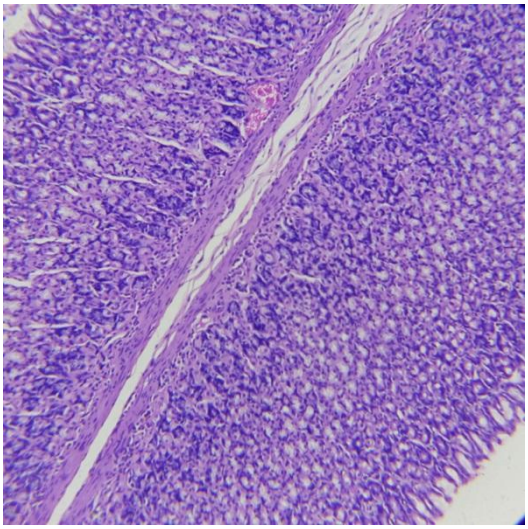

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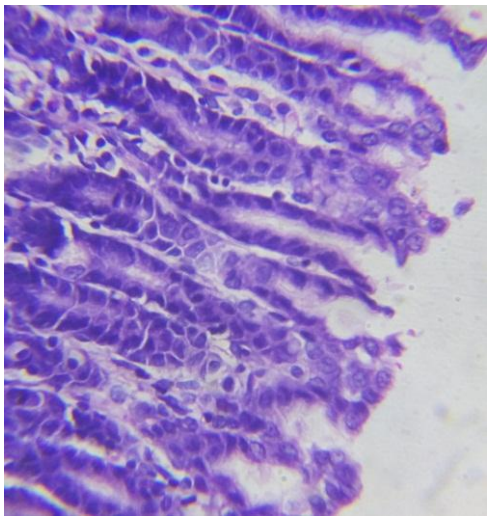
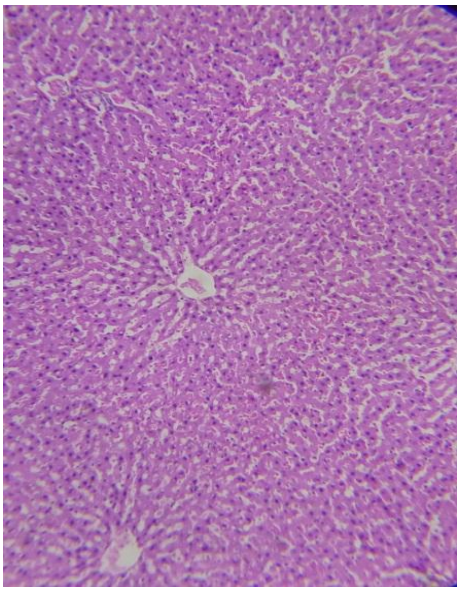


Histopathology of Liver in Sub-acute toxicity Study

Low Power Magnification 10X



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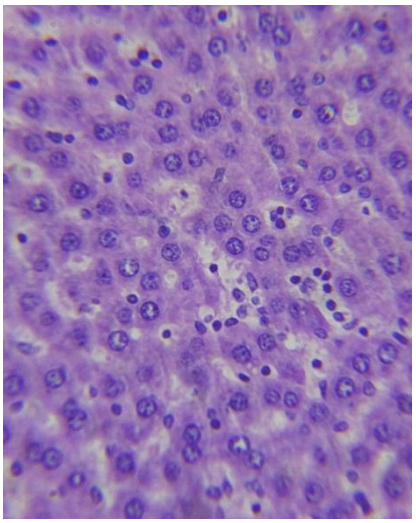

Histopathology of Kidney in Sub-acute toxicity Study

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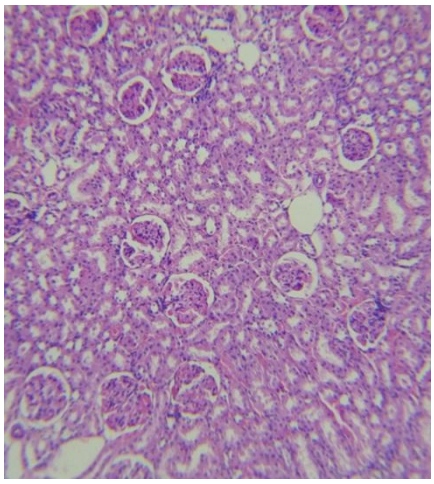

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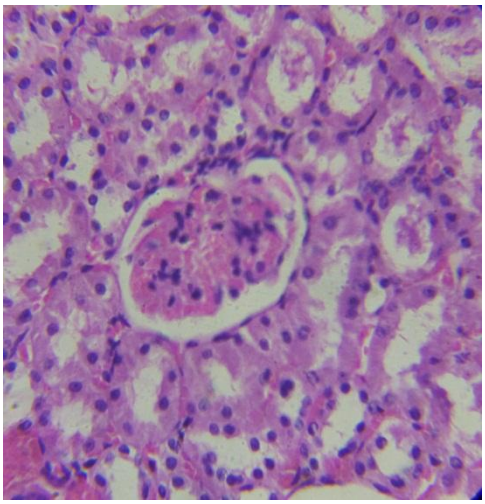
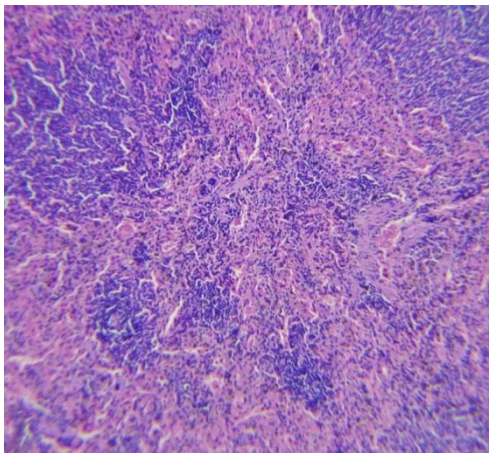


Histopathology of Spleen in Sub-acute toxicity Study

Low Power Magnification 10X



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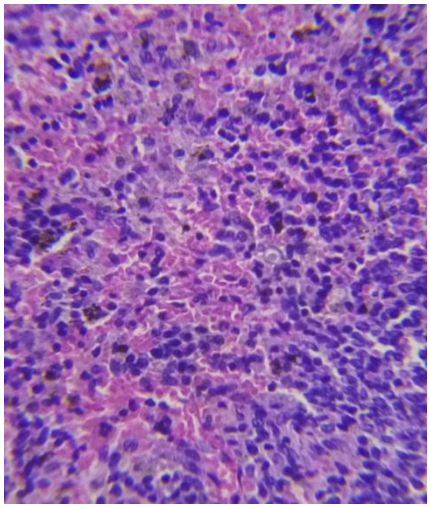
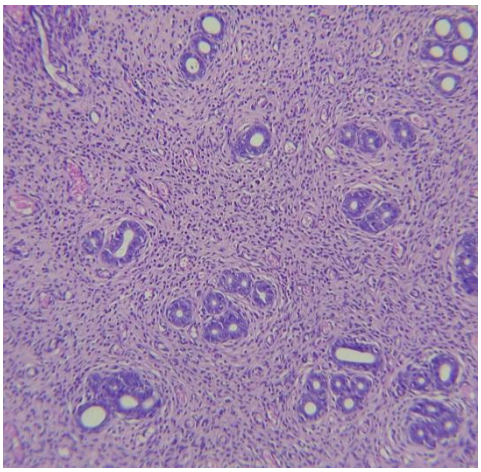


Histopathology of Uterus in Sub-acute toxicity Study

Low Power Magnification 10X



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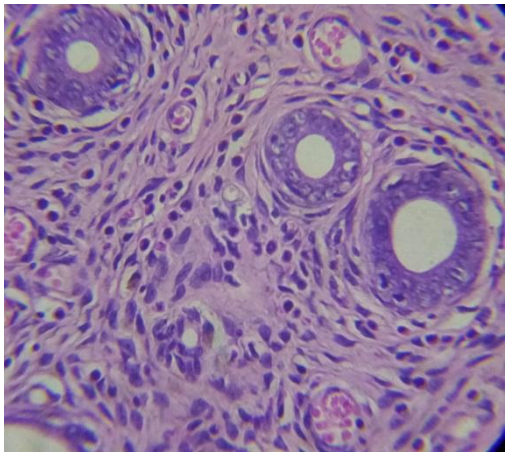
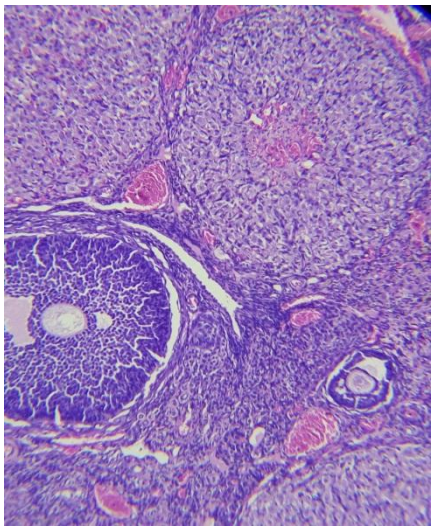


Histopathology of Ovary in Sub-acute toxicity Study

Low Power Magnification 10X



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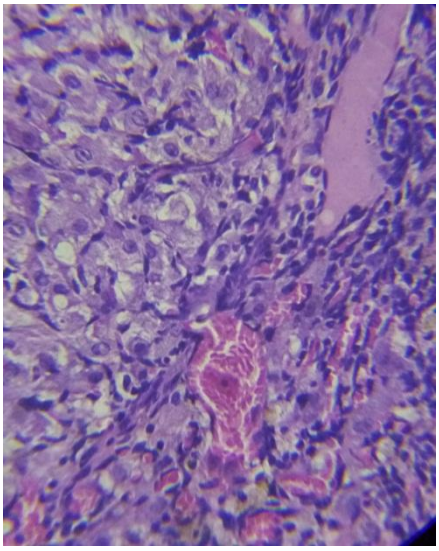


Histopathology Report

Group ID: Control Female

Brain

- No signs of pyknosis and perineural vacuolization
- No signs of edema or degeneration were observed.
- Arrangement of neurons on cerebral cortex appears normal and dense

Heart

  - No evidence of collagen deposition in myocardium.
  - Appearance of myocyte was normal

Lung

- No signs of airway secretion and bronchial secretion
- Bronchial blood vessels and connective tissue appears normal with no sings of pulmonary edema

Stomach

- No signs of ulcer and glandular degeneration were observed
- Appearance of Sub-mucosa and gastric glands appear normal

Liver

- Hepatocyte appears with dark pigment chromatin in centri lobular and periportal region
- Hepatic sinusoid and hepatic cord was normal

Kidney

- Glomerular cell integrity, basement membrane and nephrotic bundle appears normal
- No signs of lesion or inflammation were observed
- Proximal and distal convoluted tubule appears normal

Spleen

- Lymphoid follicles appears normal
- Erythropoietic cells (EP) are scattered throughout the red pulp of both the samples.

Uterus

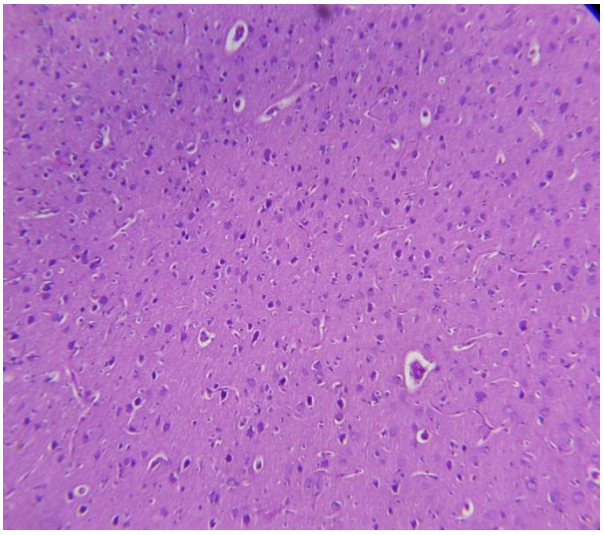
- Appearance of endometrium, myometrium and uterine glands was normal.
- Endometrial gland, epithelium and blood vessels appears normal

Ovary

- Histopathological analysis of ovary showing normal corpus luteum (CL) and Primordial follicles with few mature ovarian follicles with no signs of abnormality.

Histopathology of Brain

Low Power Magnification 10X



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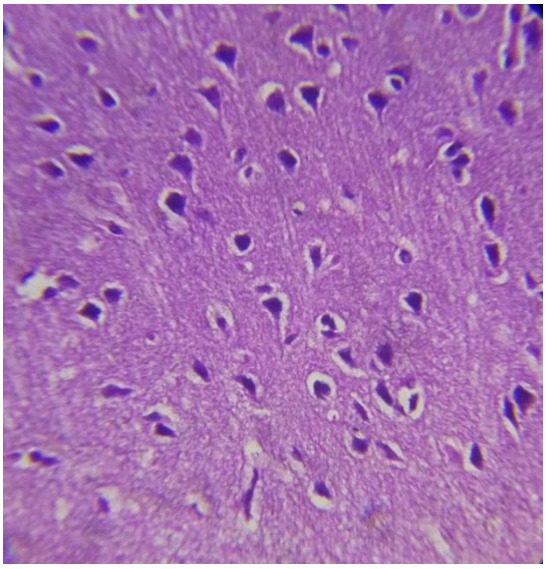
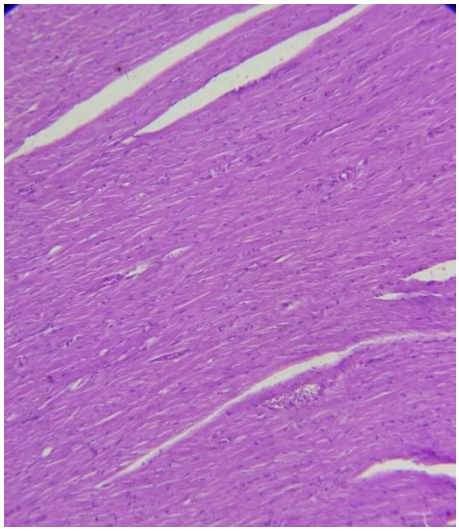


Histopathology of Heart

Low Power Magnification 10X



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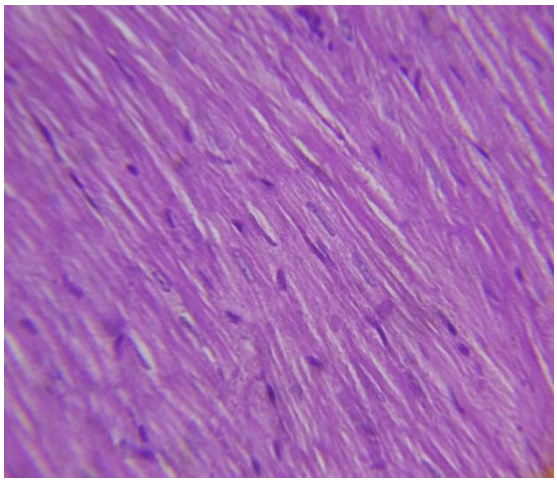
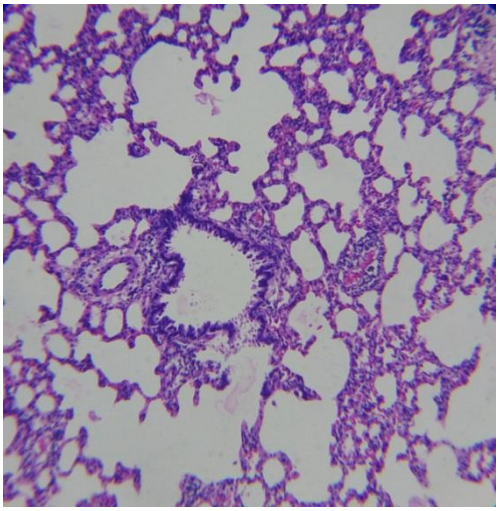


Histopathology of Lung

Low Power Magnification 10X



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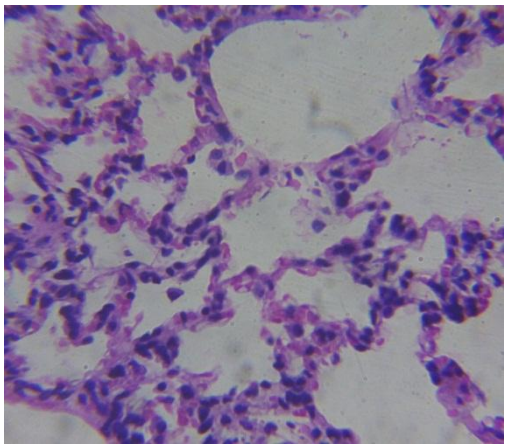
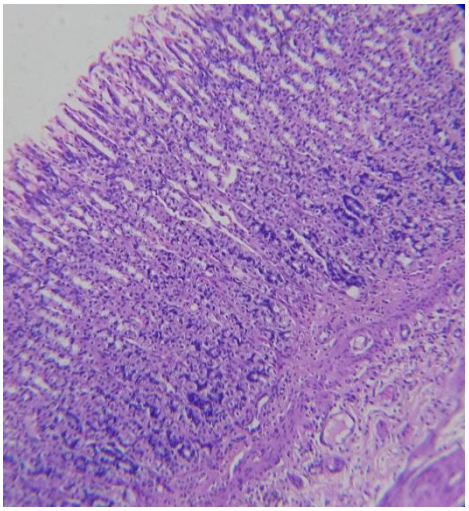


Histopathology of Stomach

Low Power Magnification 10X



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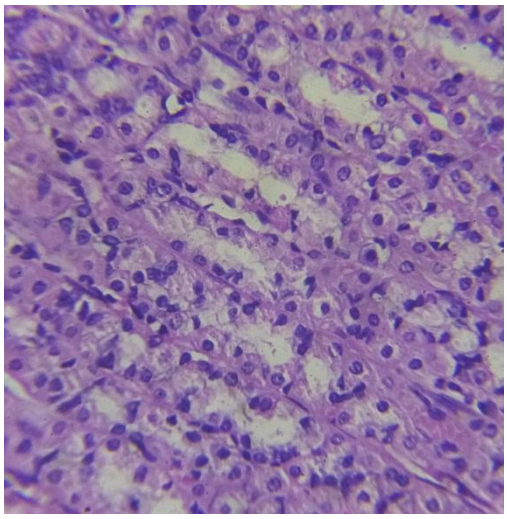
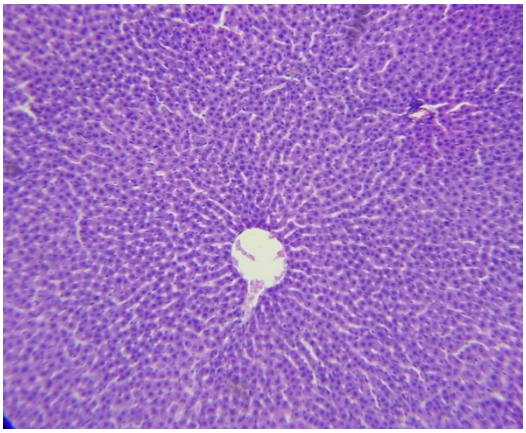
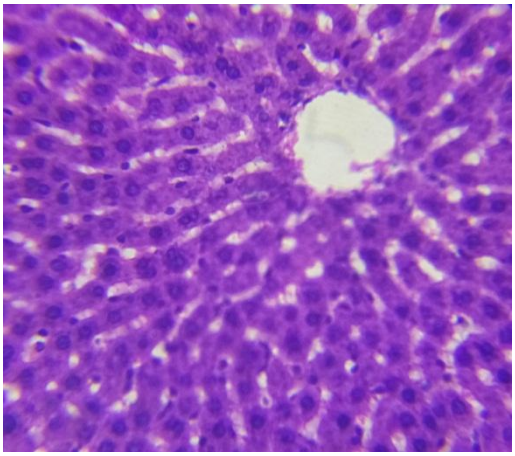


Histopathology of Liver

Low Power Magnification 10X

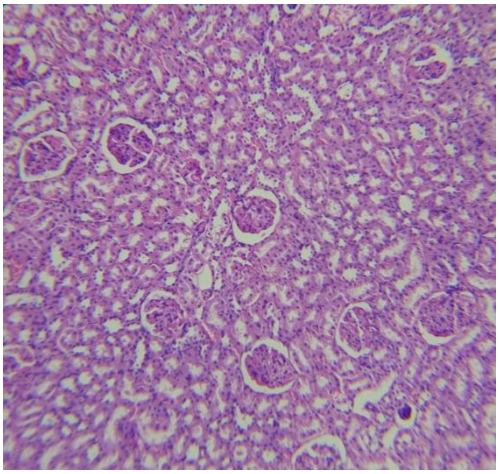


High Power Magnification 40X

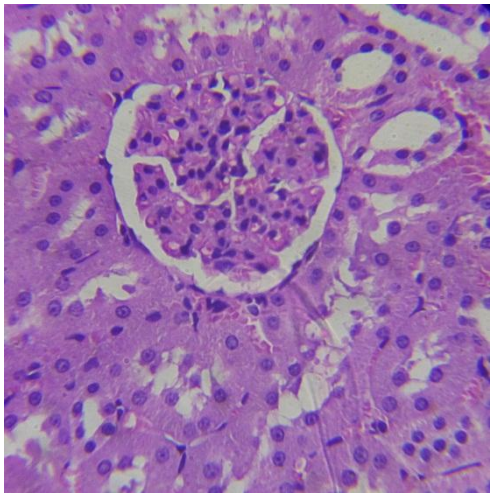


Histopathology of Kidney

Low Power Magnification 10X

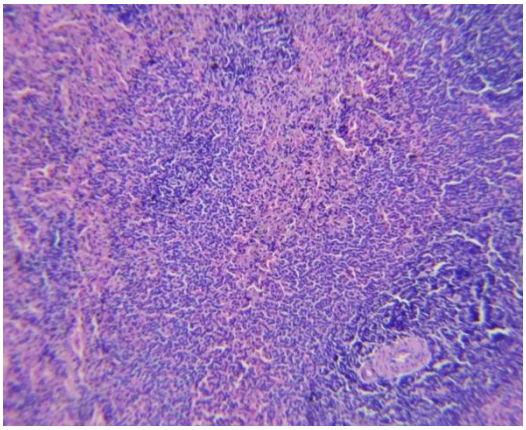


High Power Magnification 40X

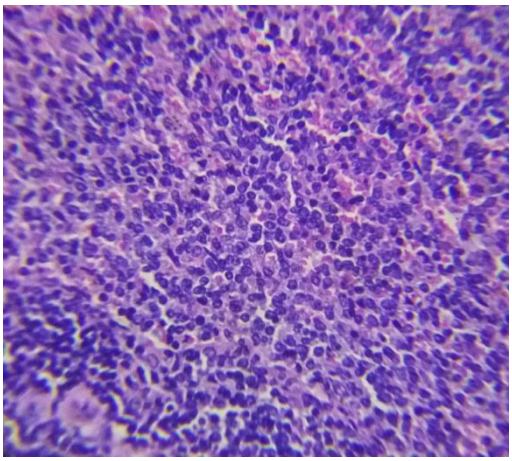


Histopathology of Spleen

Low Power Magnification 10X

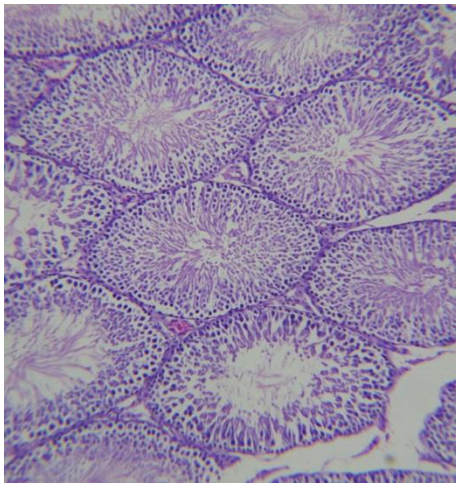


High Power Magnification 40X

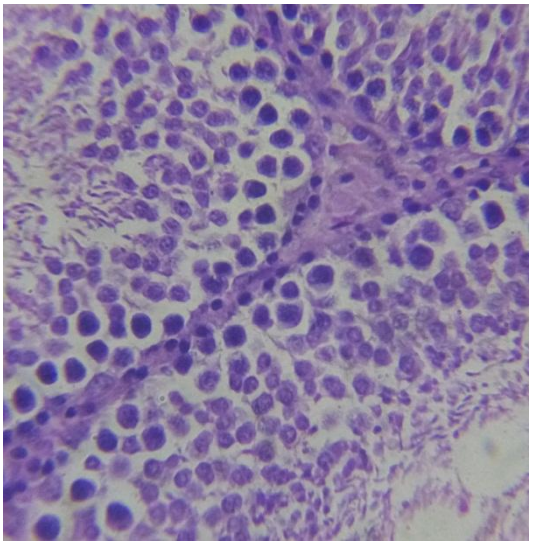


Histopathology of Testes

Low Power Magnification 10X



High Power Magnification 40X



Histopathology Report

Sample Id: Control Male

Brain

- Arrangement of the neurons appears intact with no signs of degeneration or apoptotic changes in both the samples
- Cortex region showed normal neurons with polygonal to round cell bodies containing dense cytoplasm.

Lung

- Bronchial opening appears regular with no signs of infiltration
- Appearance of alveolar network was normal
- Nucleus of type I and II alveolar cells looks normal

Heart

- Perfectly -arranged myocardial fibers, clear transverse striation and normal structure were observed.
- Appearance of cardiomyocyte was normal with dark nuclear region. The nuclei of muscle fibers appear oval arrangement

Stomach

- Gastric glands, gastric glands including secretary sheath appears normal
- Normal gastric mucosa containing intact gastric gland cells, parietal cells which are spherical cell with deeply stained dark nucleus

Spleen

- No signs of perivascular inflammation
- Appearance of splenic sinuses, Splenic cord and endothelial orientation was normal
- Appearance of LF – lymphoid follicle; PALS – periarterial lymphoid sheath was normal with no significant signs of enlargement

Liver

- Rare appearance of Kupffer cells with no evidence of phagocytosis in intracytoplasmic region
- Liver parenchyma appears normal with no evidence of necrosis
- Appearance of terminal hepatic venules (central veins) to the portal tracts was normal

Kidney

- Appearance of Podocytes and parietal epithelium in the glomeruli appears normal
- Proximal and distal convoluted tubule appears normal
- No signs of lesion or inflammation were observed
- No signs of cellular necrosis

Testes

- Histo cytology of testicular tissue shows well differentiated germ cells with respect of spermatogonia includes spermatid and sperm were observed
- Appearance of leydig cells, interstitial tissue, seminiferous tubule, Sertoli cells and spermatogonia were normal

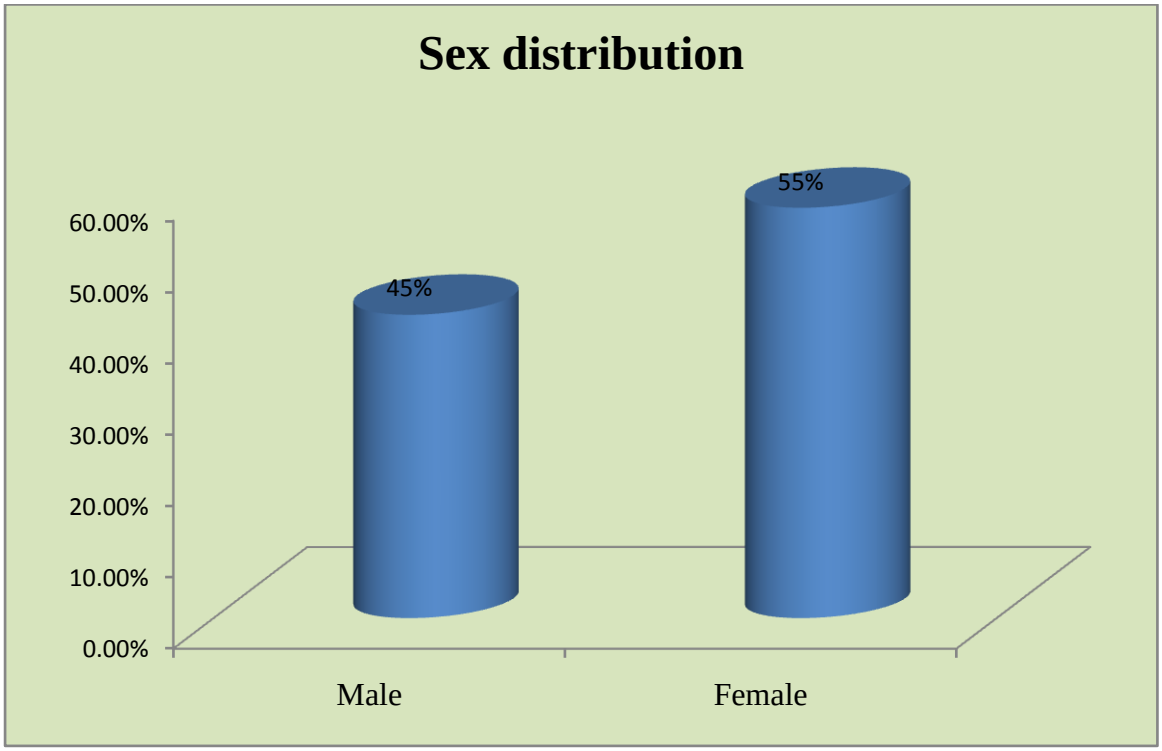
OBSERVATION AND RESULTS

The observation and results were studied and tabulated under the following heading.

1) Sex distribution
2) Age distribution
3) Occupational status
4) Family History
5) Diet habits
6) Thinai reference
7) Kaalam distribution (According to Age)
8) Kaalam distribution
9) Yakkai Ilakkanam (Physical Constitution)
10) Gunam reference
11) Duration of illness
12) Clinical features
13) Distributions of three thodams
14) Udar Kattukkal reference
15) En Vagaithervugal
16) Neerkkuri reference
17) Neikkuri reference
18) SPADI SCORE
19) Results

1. **Sex distribution:**

S.no	Sex distribution	No of cases	Percentage
1.	Male	18	45%
2.	Female	22	55%

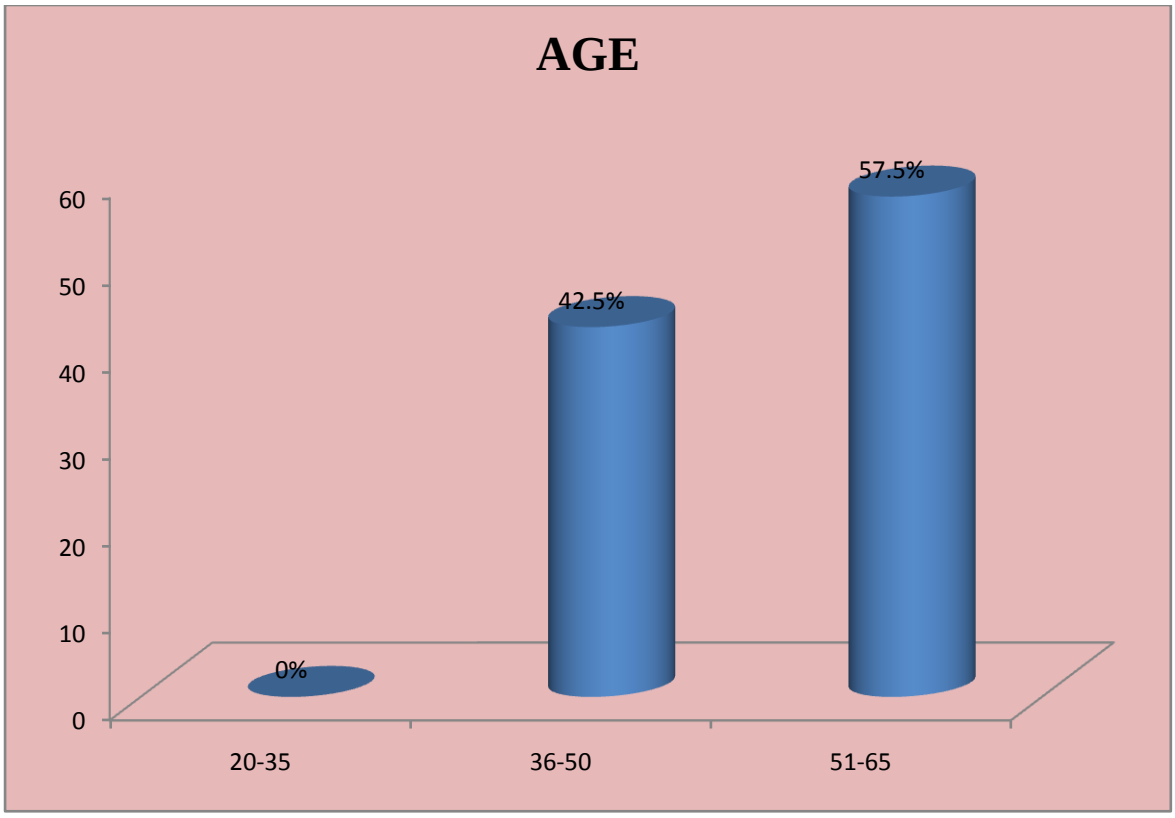


Observation:

Among the 40 patients selected for this study, 22(55%)were females and 18(45%)were males.

2. Age distribution:

S.no	Age	No of cases	Percentage
1.	20-35	-	-
2.	36-50	17	42.5%
3.	51-65	23	57.5%

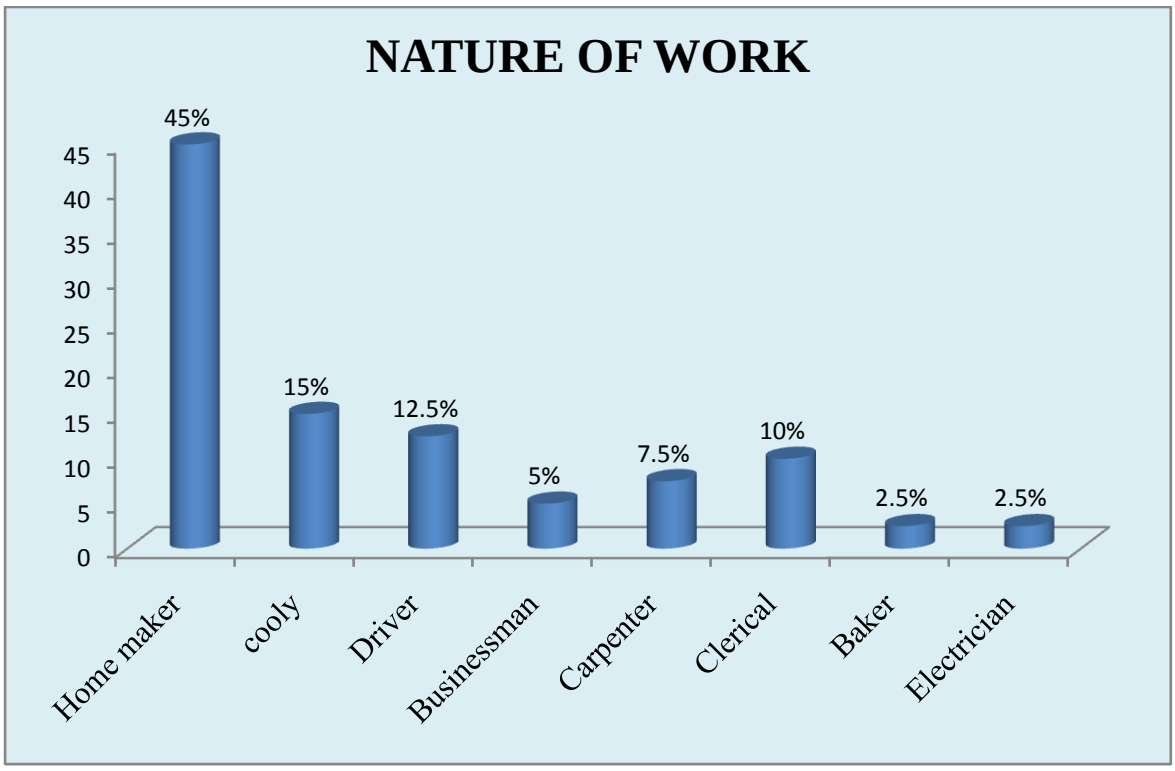


Observation:

The patients were selected from all age groups as in inclusion criteria and the maximum numbers of patients (23) 57.5% were in the age between 51 and 65yrs and (17) 42.5% patients were in the age between 36 and50 years.

3. Occupational status:

Sl. No	Nature of Work	No. of Cases	Percentage
1	Home Maker	18	45%
2	Cooley	6	15%
3	Driver	5	12.5%
4	Businessman	2	5%
5	Carpenter	3	7.5%
6	Clerical	4	10%
7	Baker	1	2.5%
8	Electrician	1	2.5%

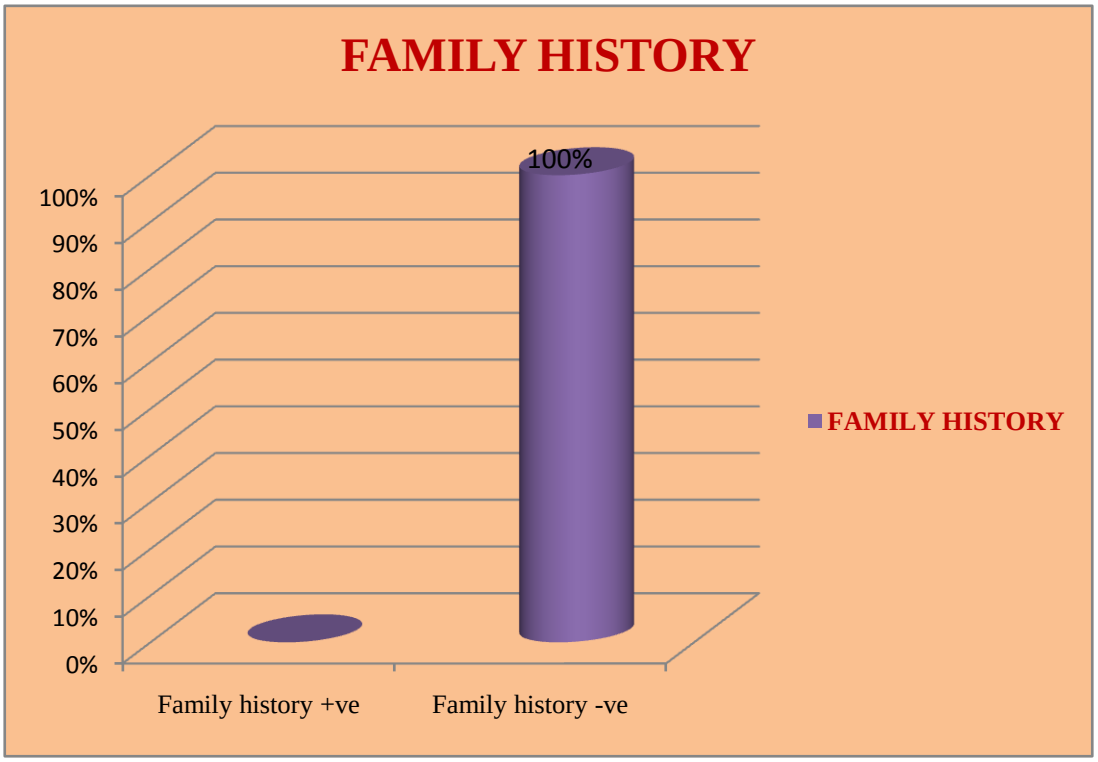


Observation:

The majority of patients in this study were home maker &cooly

4. Family history:

S.n S.no	Family history	No o No of cases	Pe Percentage
1.	Family history (+ve)	0 -	0% -
2.	Family history (-ve)	404 40	100%100%

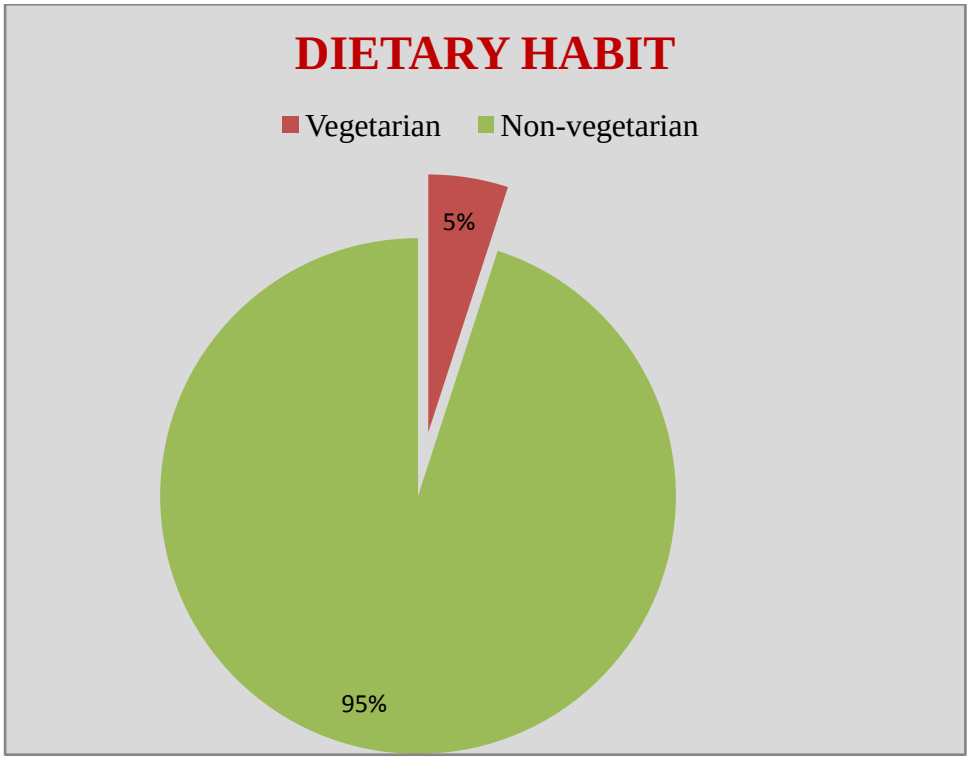


Observation:

100% of the patients showed negative family history.

5. Dietary habits:

S.no	Dietary habits	No of cases	Percentage
1.	Vegetarian	2	5%
2.	Non-vegetarian	38	95%

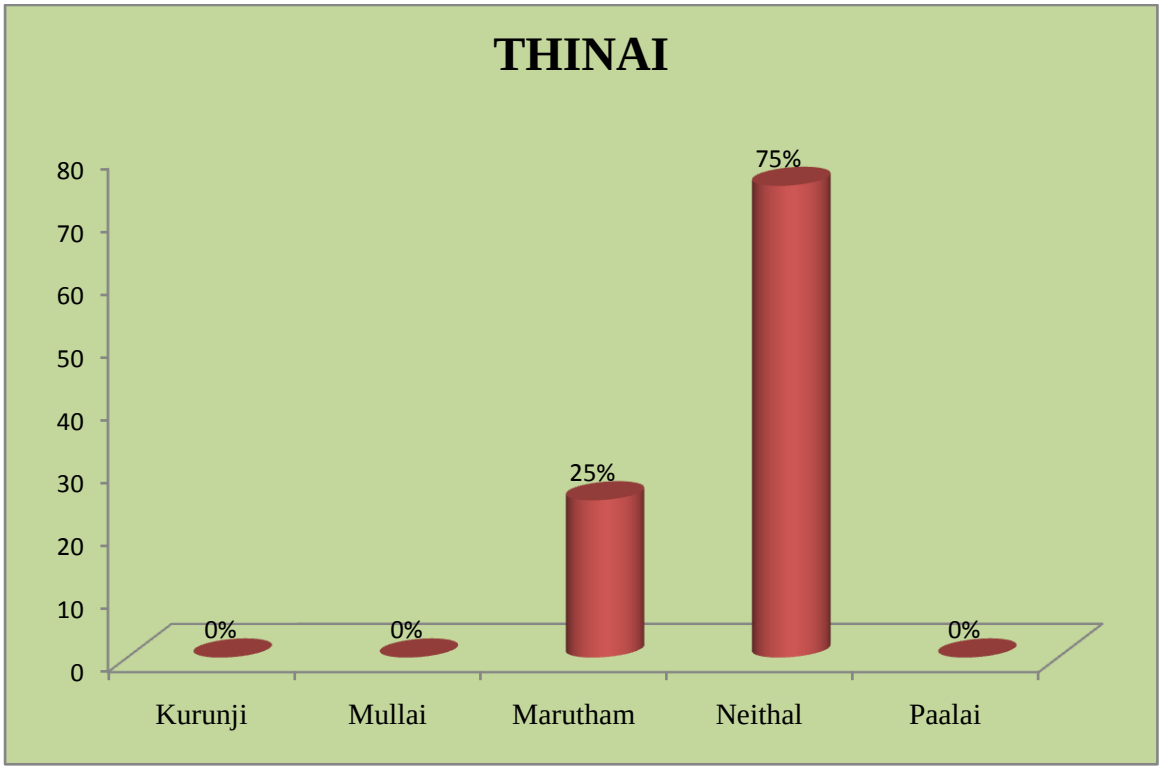


Observation:

95% of the patients were non-vegetarians.

6. Thinai distribution:

S.no	Thinai	No of cases	Percentage
1.	Kurinji	-	-
2.	Mullai	-	-
3.	Marutham	10	25%
4.	Neithal	30	75%
5.	Paalai	-	-



Observation:

75% of the patients were from *Neithal*(Coastal Area) and (25%) from *Marutham* (Fertile Land).

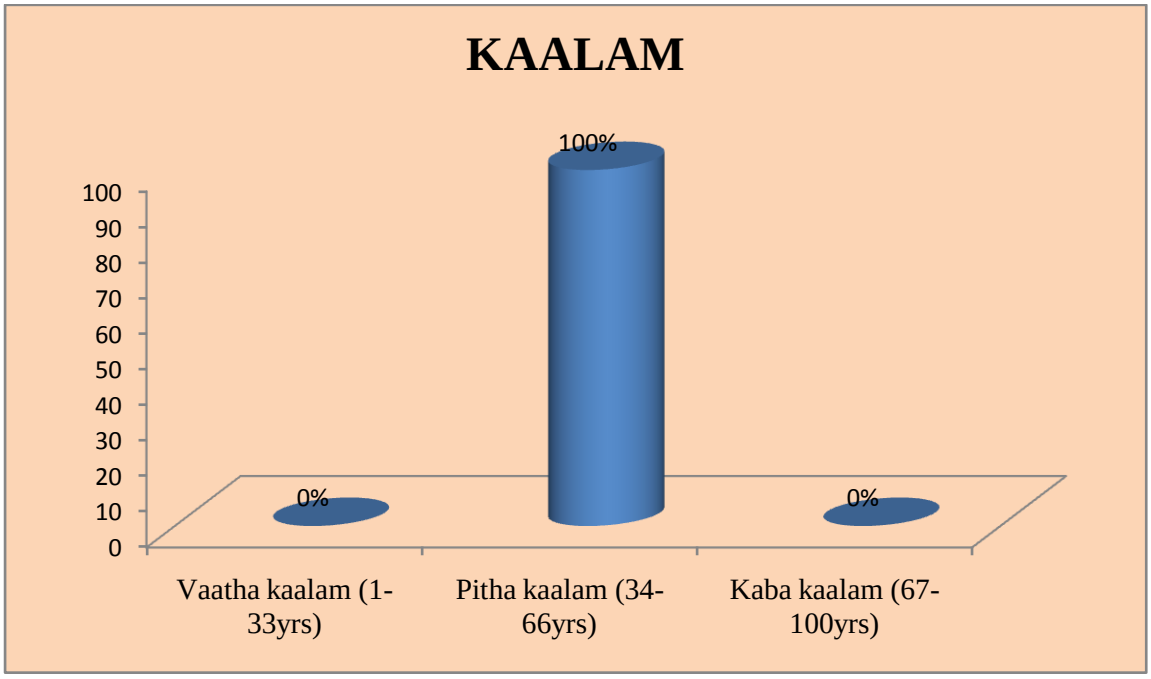
7. Kaalam distribution (According to age)

In Siddha literature human life has been divided into three periods as follows

1) *Vatham*(1-33yrs)
2) *Piththam*(34-66yrs)
3) *Kabam*(67-100yrs)

The duration of each period is said to be 33 years

S.no	Kaalam	No of cases	Percentage
1.	Vaathakaalam(1-33yrs)	-	-
2.	Pithakaalam(34-66yrs)	40	100%
3.	Kabakaalam(67-100yrs)	-	-

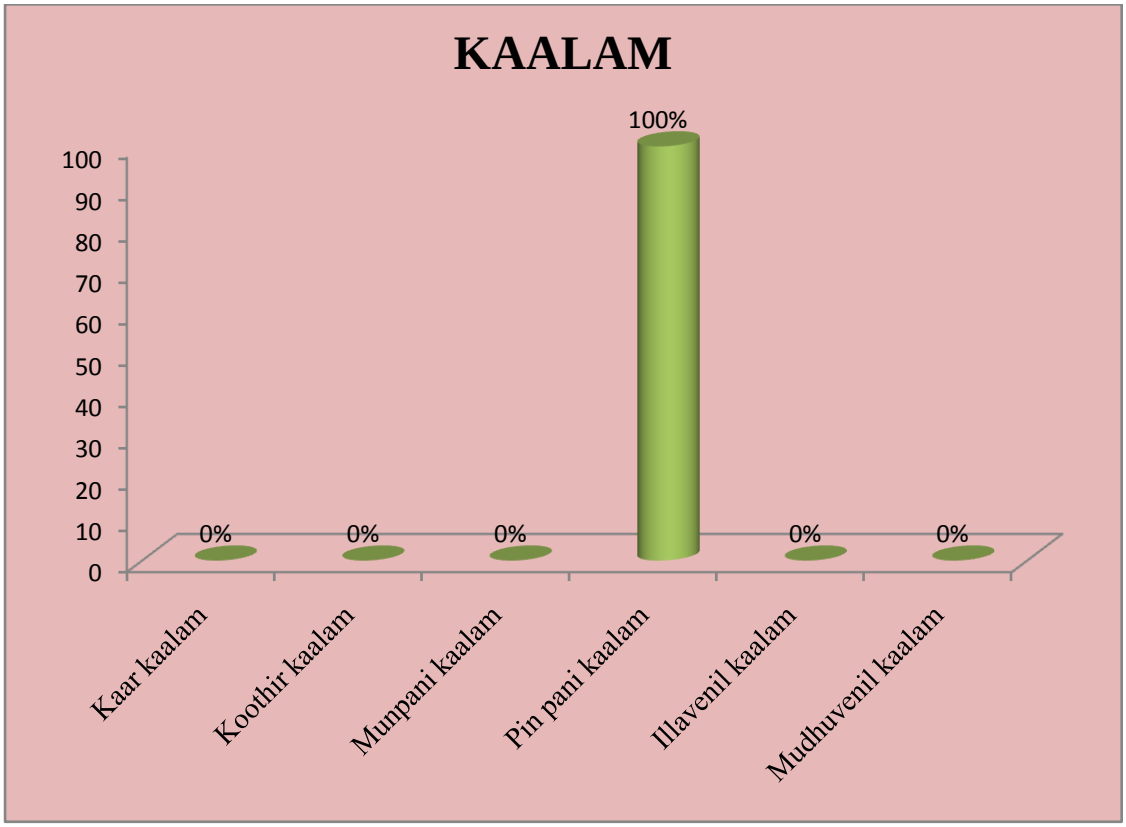


Observation:

100%of the patients were reported in *Pithakaalam*.

8. Kaalam distribution:

S.no	Kaalam distribution	No of cases	Percentage
1.	Kaarkaalam	-	-
2.	Koothirkaalam	-	-
3.	Munpanikaalam	-	-
4.	Pin panikaalam	40	100%
5.	Ilavenilkaalam	-	-
6.	Mudhuvenilkaalam	-	-

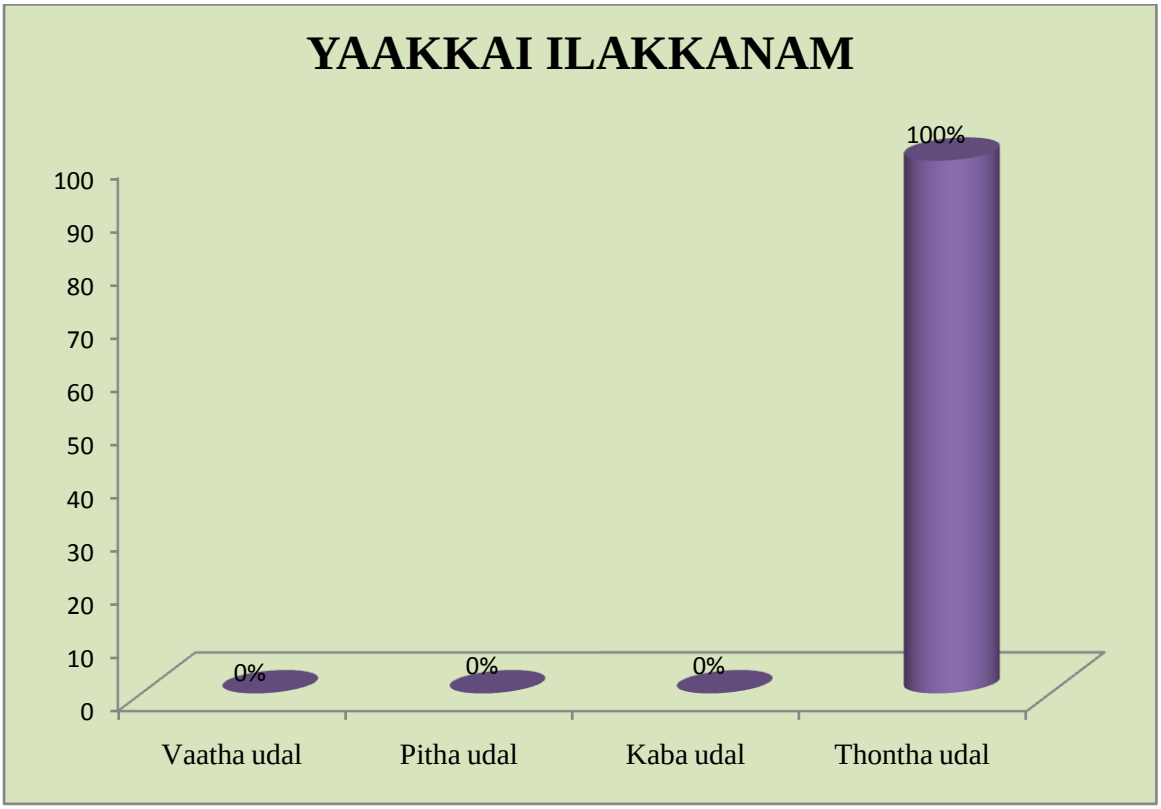


Observation:

All the patients were admitted in *Pinpanikaalam.*

9. Yaakaiilakkanam(Physical constituents):

S.no	Yaakaiilakkanam	No of cases	Percentage
1.	Vaathaudal	-	-
2.	Pithaudal	-	-
3.	Kabaudal	-	-
4.	Thonthaudal	40	100%

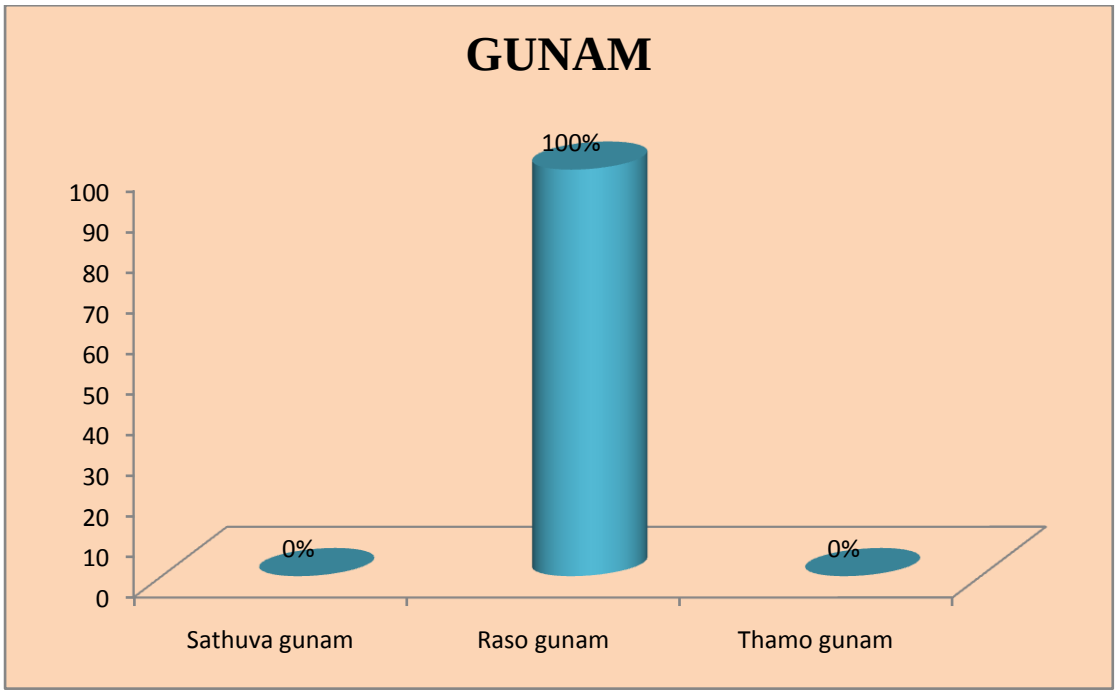


Observation:

All the patients (100%) had *ThonthaUdal*.

10. Gunam(Quality and Character)

S.no	Gunam	No of cases	Percentage
1.	Sathuvagunam	-	-
2.	Rasogunam	40	100%
3.	Thamogunam	-	-

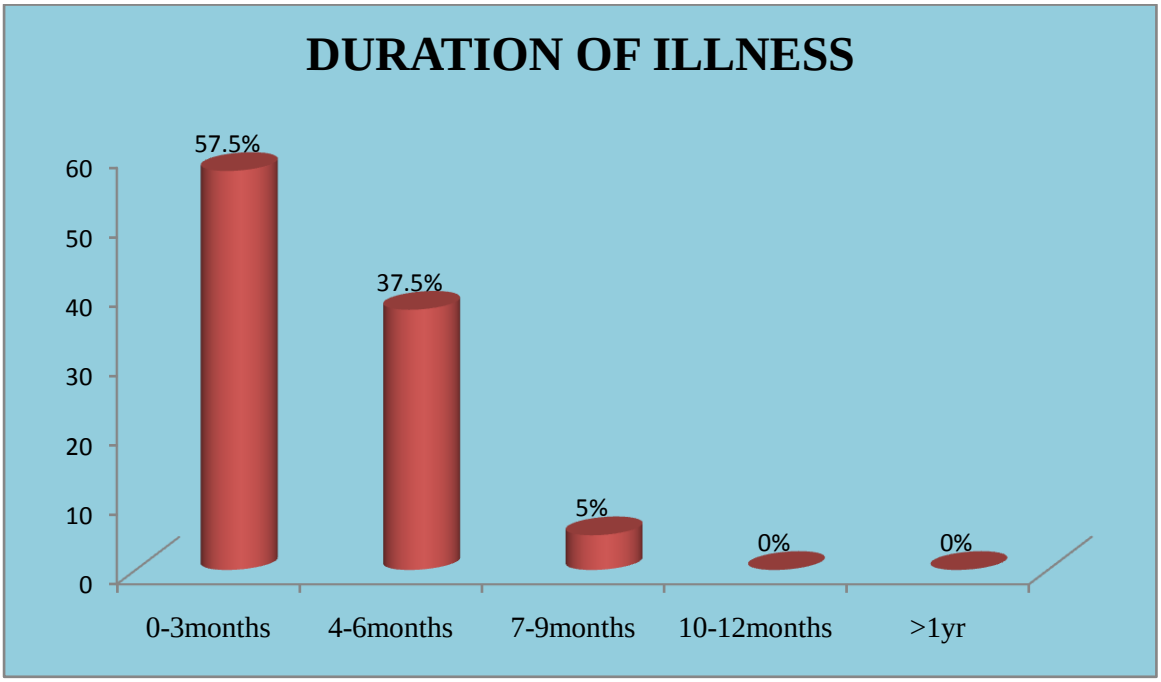


Observation:

All the patients (100%) had "*RasoGunam*".

11. Duration of illness:

S.no	Duration of illness	No of cases	Percentage
1.	0-3 months	23	57.5%
2.	4-6months	15	37.5%
3.	7-9months	2	5%
4.	10-12months	-	-
5.	>1yr	-	-

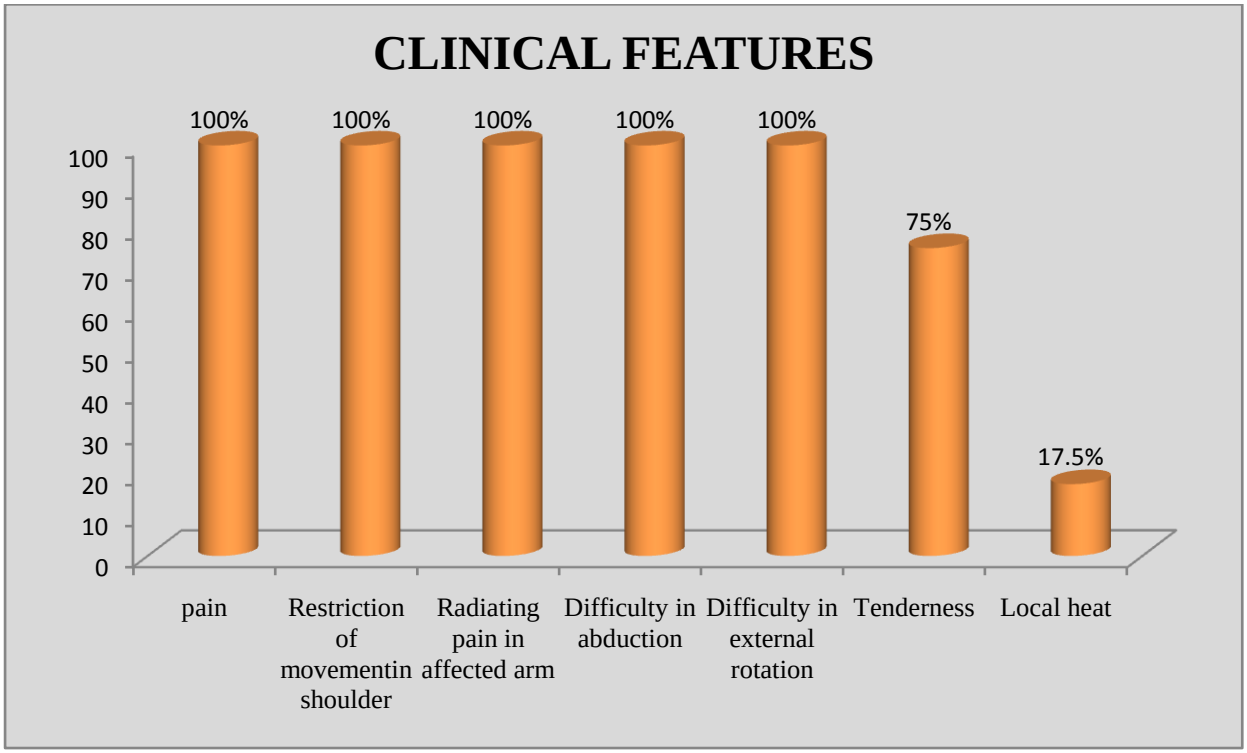


Observation:

57.5% of the patients were suffering with the illness from 0-3 months,37.5% of patients suffering with the illness from 4-6 months,5% of cases suffering from 7-9 months.

12. Clinical features:

S.no	Clinical features	No of cases	Percentage
1.	Pain	40	100%
2.	Restriction of movements in shoulder	40	100%
3.	Radiating pain in affected arm	40	100%
4.	Difficulty in abduction	40	100%
5.	Difficulty in external rotation	40	100%
6.	Tenderness	30	75%
7.	Local heat	7	17.5%

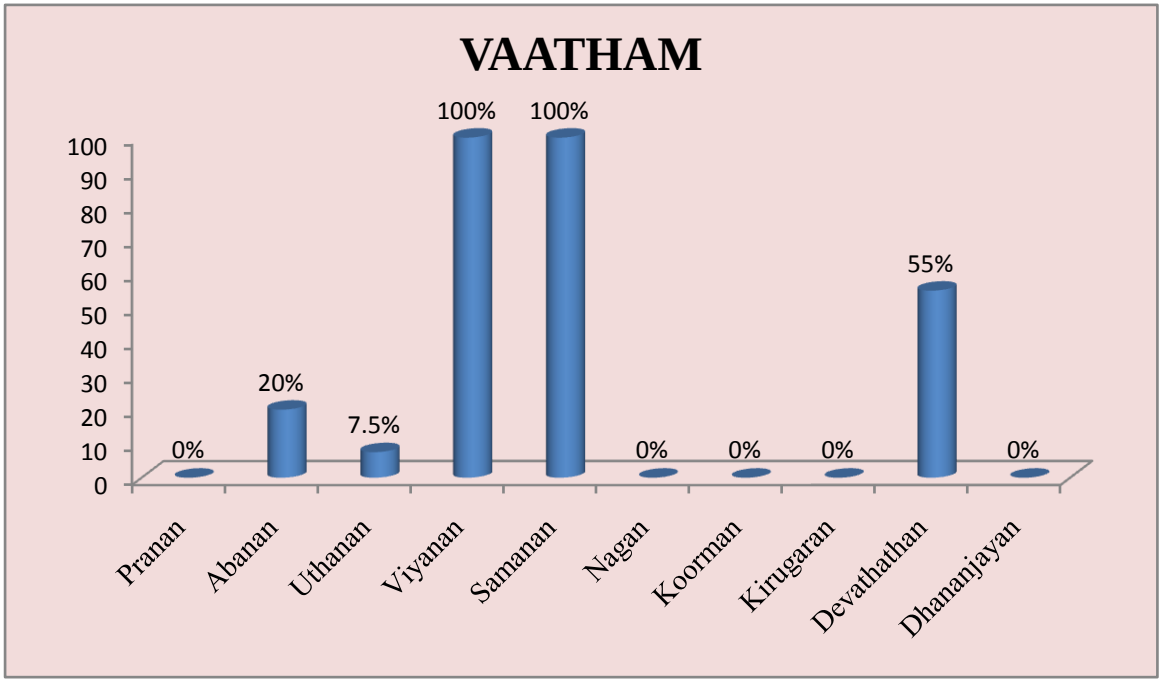


Observation:

All patients in the study had clinical features of shoulder pain, restriction of movements, radiating pain in affected arm, Abduction, external rotation in100% of cases, 75% of cases had tenderness and 17.5% of cases have local heat.

13. Distribution of Mukkutram - Vaatham:

S.no	VaatVaatham	No of of cases	no.	Perce Percentage
1	Prana	-		-
2	Abana	8		20%
3	Uthan	3		7.5%
4	Viyan	40		100%
5	Sama	40		100%
6	Nagan	-		-
7	Koorman	-		-
8	Kirugaran	-		-
9	Devadathan	22		55%
10	Dhananjayan	-		-

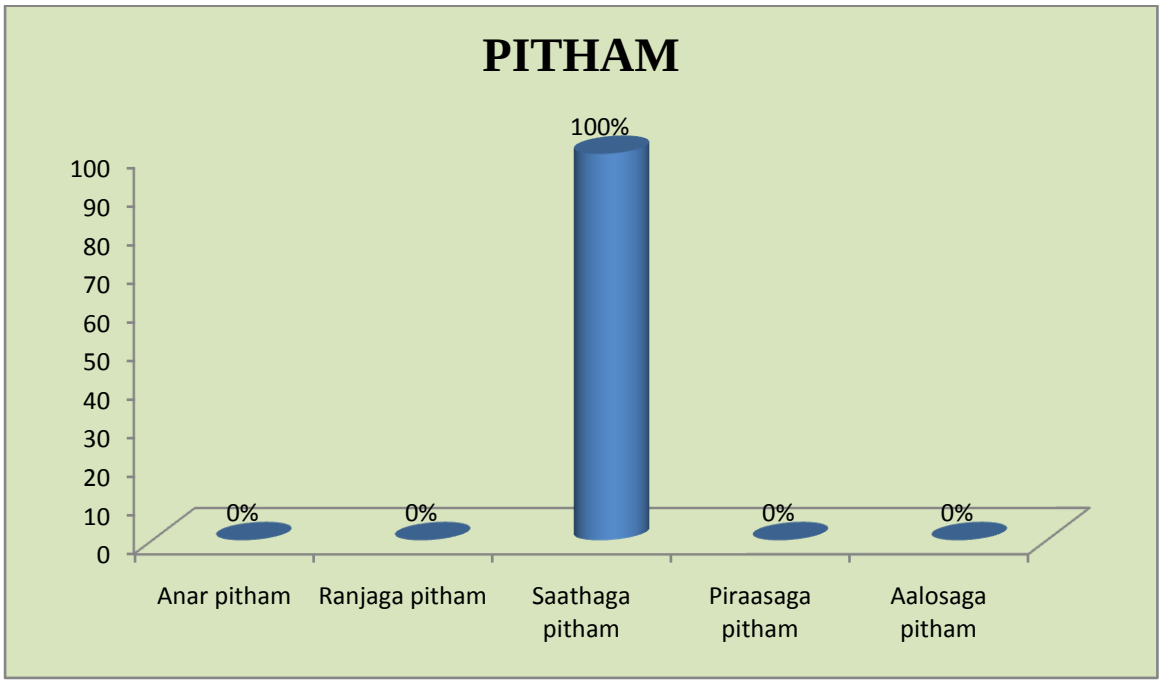


Observation:

Samaanan and *Viyaanan* were affected in all the 40 patients. *Abanan* affected in 20% of cases *Devathaththan* affected in 55% and uthanan affected in 7.5% of patients respectively.

Pitham:

S.no	PithaPitham	No of No of cases	Perce Percentage
1.		A	Nar
	Anarpitham	-	-
2.		0	0%
	Ranjagapitham	-	-
3.		40	100%
	Sathagapitham	40	100%
4.		0	0%
	Pirasagapitham	-	-
5.		0	0%
	Alosagapitham	-	-

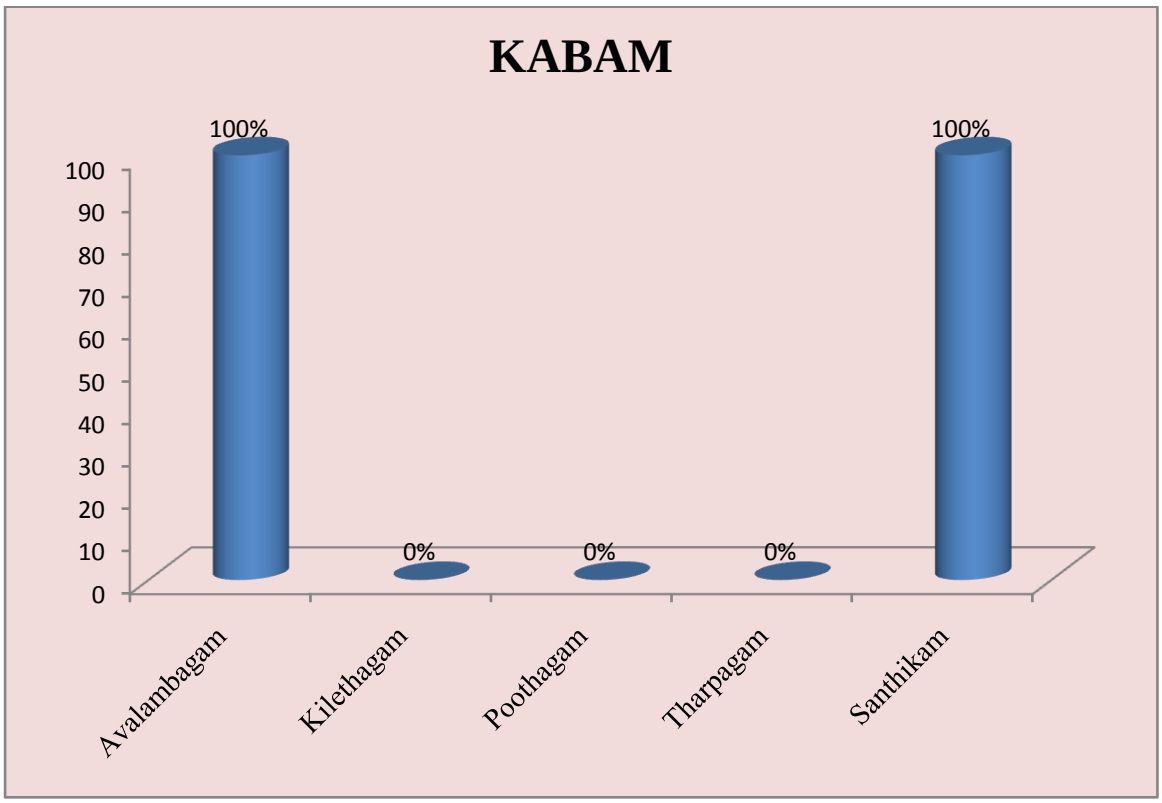


Observation:

Saathagapitham is affected in all the cases.

Kabam:

S.no S.no	Kaba Kabam	No of No of cases	Perc Percentage
1.	Avalambagam	40	100%
1		40	100%
2.	Kilethagam	0	0%
2		-	-
3.	Pothagam	0	0%
3		-	-
4.	Tharpagam	0	0%
4		-	-
5.	Santhigam	40	
5		40	100%

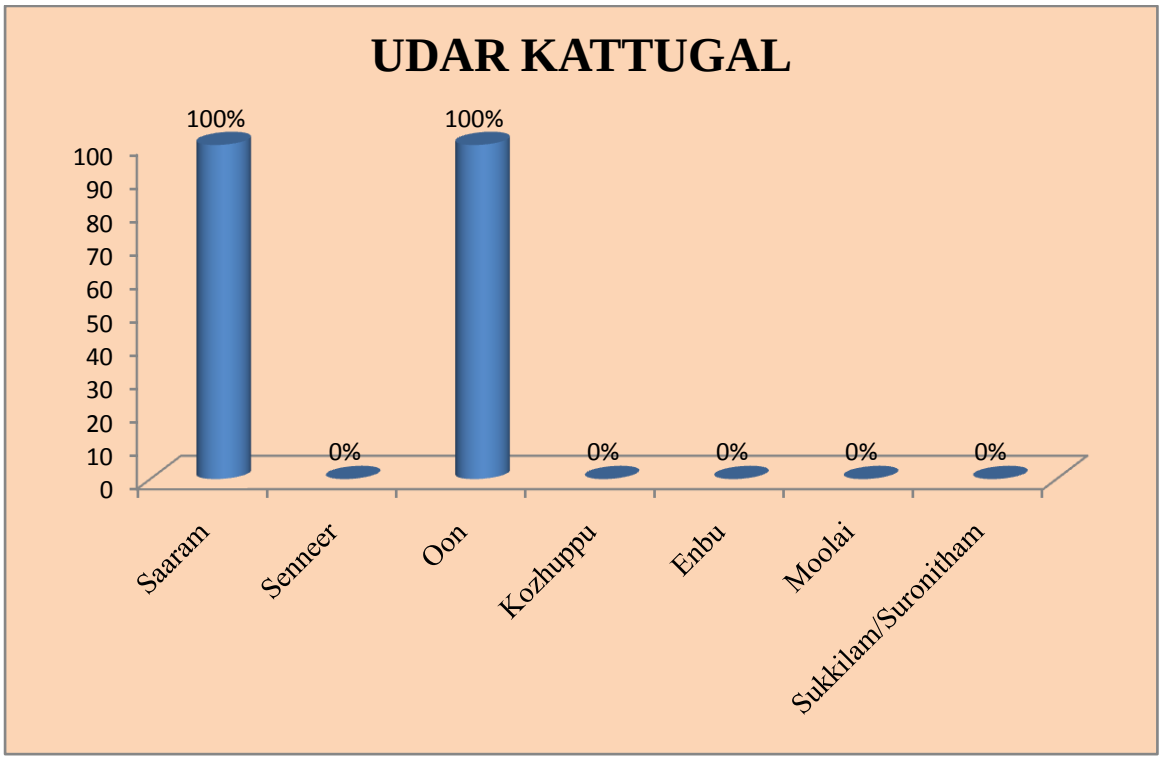


Observation:

In *Kabam Avalambagam and santhikam* affected in all cases.

14. Udarkattugal:

S.no	Udarkattugal	No of cases	Percentage
1.	Saaram	40	100%
2.	Senneer	-	-
3.	Oon	40	100%
4.	Kozhuppu	-	-
5.	Enbu	-	-
6.	Moolai	-	-
7.	Sukkilam/ Suronitham	-	-



Observation:

Among 40 patients, *Saaram* and *oon*were affected in all the cases.

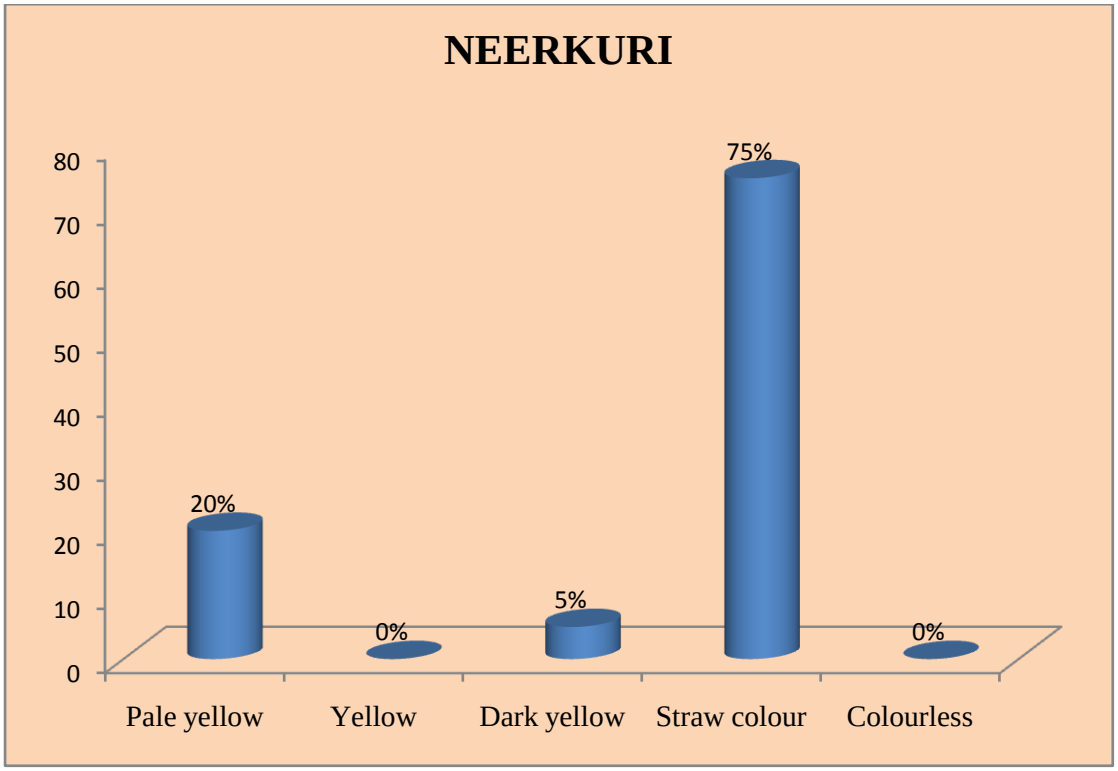
15. Envagaithervugal:

Sl. No	EnvagaiThervugal	No. of Cases	Percentage
1	Naadi		
	Vathapiththam	29	72.5%
	Piththavatham	11	27.5%
	Kabavatham	-	-
	Kabapiththam	-	-
2	Sparisam	-	-
3	Naa	-	-
4	Niram	-	-
5	Mozhi	-	-
6	Vizhi	-	-
7	Malam	8	20%
8	Moothiram	-	-

The *Naadinadai* seen in *Kumbavaatham* patients were *Vathapitham*(72.5%), *Pithavatham(*27.5 %).

16. Neerkuri Reference:

S.no S.no	Neerkuri	No of	No of cases	Perce	Percentage
1.	Pale y Pale yellow	8		20%	
1		8		20%	
2.	Yello Yellow	0		0%	
2		-		-	
3.	Dark Dark yellow	2		5%	
3		2		5%	
4.	Straw Straw colour	30		75%	
4		30		75%	
5.	Colou Colourless	0		0%	
5		-		-	

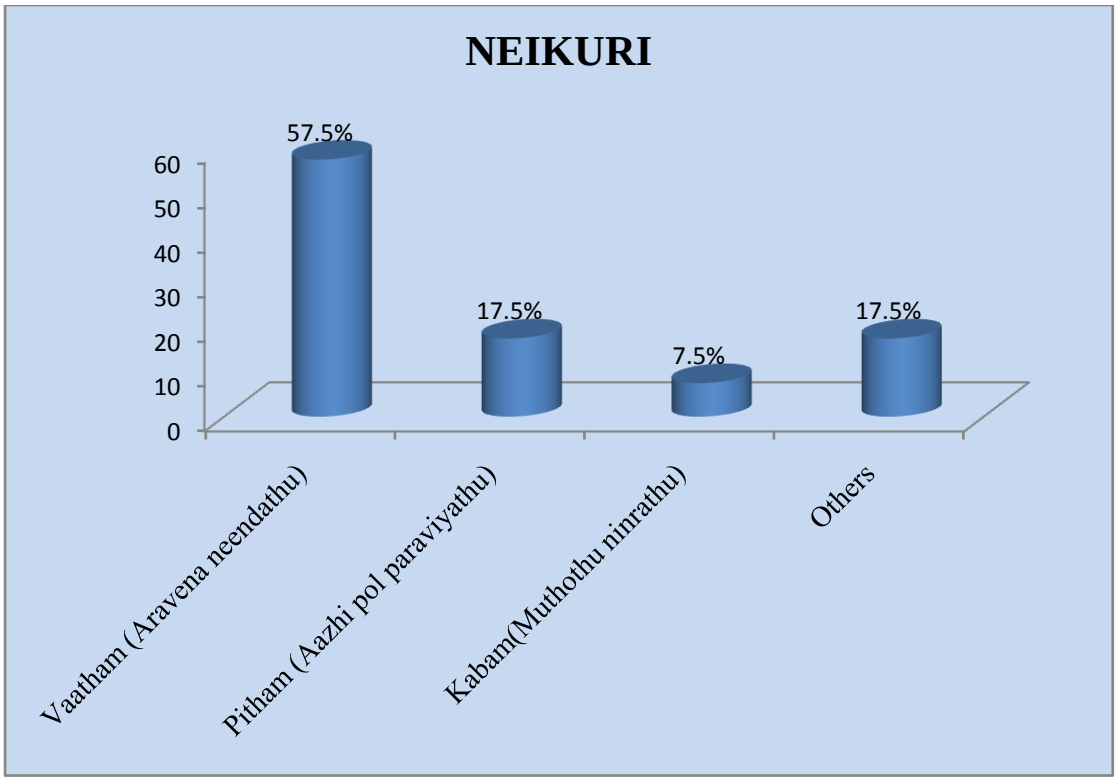


Observation:

In this study 50% of the patients had *straw* yellow, 20% with pale yellow, and5% with dark yellow .

17. Neikuri Reference:

S.no	Neikuri	No of cases	Percentage
1.	Vaatham(Aravenaneendathu)	23	57.5%
2.	Pitham(Aazhi pol paraviyathu)	7	17.5%
3.	Kabam(Muthothuninrathu)	3	7.5%
4.	Others	7	17.5%



Observation:

In this study 57.5% of the patients had *Neikuri* with *Vatham (Aravana Neendal),* 17.5% with *Piththam (Aazhipol Paraviyathu),* 7.5% with *Kabam (Muththothu ninrathu)* and 17.5% with other pattern.

18 .SPADI SCORE (Pain scale) – With Varmam(Group A)

S.NO	OP/IP NO	NAME	AGE/ SEX	BT(%)	AT (%)	RESULT
1	H40776	Mr.Dhandapani	62/M	74	22	GOOD
2	9461	Mr.P.Babu	57/M	82	34	MODERATE
3	I64222	Mrs.V.Mangai	43/F	72	18	GOOD
4	8825	Mrs.Maheshwari	60/F	88	62	MODERATE
5	I69664	Mr.T.M.Kumar	58/M	82	10	GOOD
6	I03771	Mrs.Bakyamary	60/F	94	30	GOOD
7	8858	Mrs.Indirani	50/F	90	10	VERY GOOD
8	8859	Mrs.Vasanthi	64/F	86	14	GOOD
9	I50208	Mr.P.V.sundarraj	54/M	72	16	GOOD
10	I70853	Mr.Elamvazhuthi	61/M	78	18	GOOD
11	H91187	Mr.Sugumar	37/M	92	30	GOOD
12	G75398	Mrs.Maheshwari	50/F	84	8	VERY GOOD
13	I61037	Mrs.Sumathi	50/F	76	10	GOOD
14	I69442	Mrs.Mangayarthilagam	60/F	78	12	GOOD
15	I88148	Mr.Iyyadurai	42/M	76	6	GOOD
16	9557	Mrs.Thulasigam	55/F	82	14	GOOD
17	I85923	Mr.Kandhasami	43/M	82	4	VERY GOOD
18	I66909	Mr.Nagaraj	38/M	82	5	GOOD
19	I70825	Mr.C.Nagarajan	60/M	90	48	MODERATE
20	8909	Mrs.Meenatchi	57/F	92	4	VERY GOOD

SPADI SCORE (Disability scale) – With Varmam (Group A)

S.NO	OP/IP NO	NAME	AGE/ SEX	BT(%)	AT (%)	RESULT
1	H40776	Mr.Dhandapani	62/M	75	12.5	GOOD
2	9461	Mr.P.Babu	57/M	82	23.75	GOOD
3	I64222	Mrs.V.Mangai	43/F	64	15	GOOD
4	8825	Mrs.Maheshwari	60/F	80	61.25	MILD
5	I69664	Mr.T.M.Kumar	58/M	81.25	6.25	GOOD
6	I03771	Mrs.Bakyamary	60/F	83.75	15	GOOD
7	8858	Mrs.Indirani	50/F	80	13.75	GOOD
8	8859	Mrs.Vasanthi	64/F	80	22.5	GOOD
9	I50208	Mr.P.V.sundarraj	54/M	71.25	10	GOOD
10	I70853	Mr.Elamvazhuthi	61/M	72.5	12.5	GOOD
11	H91187	Mr.Sugumar	37/M	85	16.25	GOOD
12	G75398	Mrs.Maheshwari	50/F	80	8.75	GOOD
13	I61037	Mrs.Sumathi	50/F	71.25	6.25	GOOD
14	I69442	Mrs.Mangayarthilagam	60/F	73.75	12.5	GOOD
15	I88148	Mr.Iyyadurai	42/M	72.5	13.75	GOOD
16	9557	Mrs.Thulasigam	55/F	77.5	6.25	GOOD
17	I85923	Mr.Kandhasami	43/M	82.5	6.25	VERY GOOD
18	I66909	Mr.Nagaraj	38/M	78.75	10	GOOD
19	I70825	Mr.C.Nagarajan	60/M	82.5	48.75	MODERATE
20	8909	Mrs.Meenatchi	57/F	87.5	8.75	VERY GOOD

SPADI SCORE (Total score) – With Varmam (Group A)

S.NO	OP/IP NO	NAME	AGE/ SEX	BT(%)	AT (%)	RESULT
1	H40776	Mr.Dhandapani	62/M	74.61	15.96	GOOD
2	9461	Mr.P.Babu	57/M	82.3	27.69	GOOD
3	I64222	Mrs.V.Mangai	43/F	76.92	16.15	GOOD
4	8825	Mrs.Maheshwari	60/F	83	61.5	MILD
5	I69664	Mr.T.M.Kumar	58/M	81.53	7.69	GOOD
6	I03771	Mrs.Bakyamary	60/F	87.69	20.76	GOOD
7	8858	Mrs.Indirani	50/F	78.46	12.30	GOOD
8	8859	Mrs.Vasanthi	64/F	82.30	19.23	GOOD
9	I50208	Mr.P.V.Sundarraj	54/M	71.53	8.46	GOOD
10	I70853	Mr.Elamvazhuthi	61/M	74.6	13.84	GOOD
11	H91187	Mr.Sugumar	37/M	87.69	21.53	GOOD
12	G75398	Mrs.Maheshwari	50/F	81.53	8.46	GOOD
13	I61037	Mrs.Sumathi	50/F	73.07	7.69	GOOD
14	I69442	Mrs.Mangayarthilagam	60/F	75.38	12.30	GOOD
15	I88148	Mr.Iyyadurai	42/M	73.84	10.76	GOOD
16	9557	Mrs.Thulasigam	55/F	79.23	9.23	GOOD
17	I85923	Mr.Kandhasami	43/M	82.30	5.38	VERY GOOD
18	I66909	Mr.Nagaraj	38/M	80	10	GOOD
19	I70825	Mr.C.Nagarajan	60/M	85.38	48.46	GOOD
20	8909	Mrs.Meenatchi	57/F	89.23	6.92	VERY GOOD

SPADI SCORE (Pain scale) - With Trial medicines (Group-B)

S.NO	OP/IP NO	NAME	AGE/ SEX	BT(%)	AT (%)	RESULT
1	C20391	Mr.K.Thirumaran	56/M	70	16	GOOD
2	I41274	Mrs.M.Bhavani	40/F	70	14	GOOD
3	I39463	Mrs.B.Jeeva	52/F	72	8	GOOD
4	I37612	Mr.C.Mani	52/M	76	16	GOOD
5	F043532	Mrs.Govinthammal	38/F	84	42	MODERATE
6	H78671	Mrs.Nirmala	53/F	72	10	GOOD
7	I24657	Mr.B.PareshBehera	55/M	88	46	MODERATE
8	I68182	Mr.Rajasekaran	36/M	86	44	MODERATE
9	G20673	Mrs.N.Meerabegam	45/F	72	22	MODERATE
10	I69546	Mrs.Muthulakshmi	52/F	78	38	MODERATE
11	H9339	Mrs.Selvakumari	58/F	80	30	GOOD
12	F54907	Mr.Thangappan	59/M	78	16	GOOD
13	I5160	Mrs.Muthukili	40/F	92	48	MODERATE
14	G41863	Mrs.R.Kannagi	48/F	92	32	GOOD
15	I31482	Mrs.R.K.Indrani	43/F	90	14	VERYGOOD
16	I48564	Mr.P.Sokkuvel	62/M	92	17	GOOD
17	H37544	Mr.D.Kalavathy	64/M	74	32	MODRATE
18	I72321	Mr.K.Kumar	42/M	84	42	MODERATE
19	H63909	Mrs.B.Srimathi	42/F	94	4	MODERATE
20	I7770	Mrs.Amsavani	63/F	82	22	GOOD

SPADI SCORE (Disability scale) - With Trial medicines (Group-B)

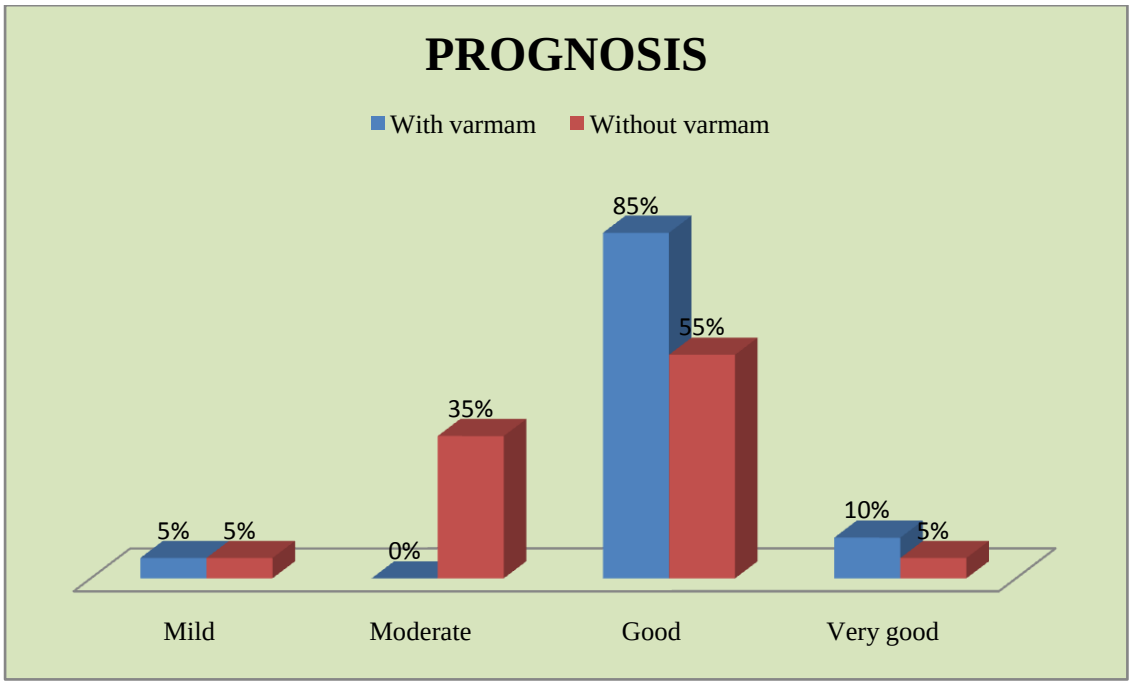
S.NO	OP/IP NO	NAME	AGE/ SEX	BT(%)	AT (%)	RESULT
1	C20391	Mr.K.Thirumaran	56/M	71.25	15	GOOD
2	I41274	Mrs.M.Bhavani	40/F	67.5	13.75	GOOD
3	I39463	Mrs.B.Jeeva	52/F	70	11.25	GOOD
4	I37612	Mr.C.Mani	52/M	81.25	32.5	MODERATE
5	F043532	Mrs.Govinthammal	38/F	77.5	37.5	MODERATE
6	H78671	Mrs.Nirmala	53/F	83.75	23.75	GOOD
7	I24657	Mr.B.PareshBehera	55/M	82.5	37.5	MODERATE
8	I68182	Mr.Rajasekaran	36/M	86.25	27.5	GOOD
9	G20673	Mrs.N.Meerabegam	45/F	85	26.25	GOOD
10	I69546	Mrs.Muthulakshmi	52/F	68.75	33.75	MODERATE
11	H9339	Mrs.Selvakumari	58/F	78.75	27.5	MODERATE
12	F54907	Mr.Thangappan	59/M	81.25	20	GOOD
13	I5160	Mrs.Muthukili	40/F	85	46.25	MODERATE
14	G41863	Mrs.R.Kannagi	48/F	82.5	42.5	MODERATE
15	I31482	Mrs.R.K.Indrani	43/F	85	16.25	GOOD
16	I48564	Mr.P.Sokkuvel	62/M	80	37.5	MODERATE
17	H37544	Mr.D.Kalavathy	64/M	80	36.25	MODRATE
18	I72321	Mr.K.Kumar	42/M	77.5	37.5	MODERATE
19	H63909	Mrs.B.Srimathi	42/F	87.5	11.5	VERY GOOD
20	I7770	Mrs.Amsavani	63/F	81.25	28.75	GOOD

SPADI SCORE (Total) - With Trial medicines (Group-B)

S.NO	OP/IP NO	NAME	AGE/ SEX	BT(%)	AT (%)	RESULT
1	C20391	Mr.K.Thirumaran	56/M	70.76	15.38	GOOD
2	I41274	Mrs.M.Bhavani	40/F	68.46	13.84	GOOD
3	I39463	Mrs.B.Jeeva	52/F	70	10	GOOD
4	I37612	Mr.C.Mani	52/M	79.25	26.15	GOOD
5	F043532	Mrs.Govinthammal	38/F	80	39.23	MODERATE
6	H78671	Mrs.Nirmala	53/F	79.23	18.46	GOOD
7	I24657	Mr.B.PareshBehera	55/M	84.61	40.76	MODERATE
8	I68182	Mr.Rajasekaran	36/M	86.15	33.84	GOOD
9	G20673	Mrs.N.Meerabegam	45/F	80	24.61	GOOD
10	I69546	Mrs.Muthulakshmi	52/F	72.30	50	MILD
11	H9339	Mrs.Selvakumari	58/F	78.87	26.15	GOOD
12	F54907	Mr.Thangappan	59/M	80	18.46	GOOD
13	I5160	Mrs.Muthukili	40/F	80	46.92	MODERATE
14	G41863	Mrs.R.Kannagi	48/F	86.1	38.4	MODERATE
15	I31482	Mrs.R.K.Indrani	43/F	86.92	15.38	GOOD
16	I48564	Mr.P.Sokkuvel	62/M	84.61	36.1	MODERATE
17	H37544	Mr.D.Kalavathy	64/M	77.69	34.61	MODERATE
18	I72321	Mr.K.Kumar	42/M	80	39.23	MODERATE
19	H63909	Mrs.B.Srimathi	42/F	90	8.46	VERY GOOD
20	I7770	Mrs.Amsavani	63/F	81.53	26.15	GOOD

18. PROGNOSIS(WITH VARMAM and WITHOUT VARMAM):

Prognosis			Without varmam	
Total score	No of patients	Percentage	No of patients	Percentage
Mild	1	5%	1	5%
Moderate	-	-	7	35%
Good	17	85%	11	55%
Very good	2	10%	1	5%



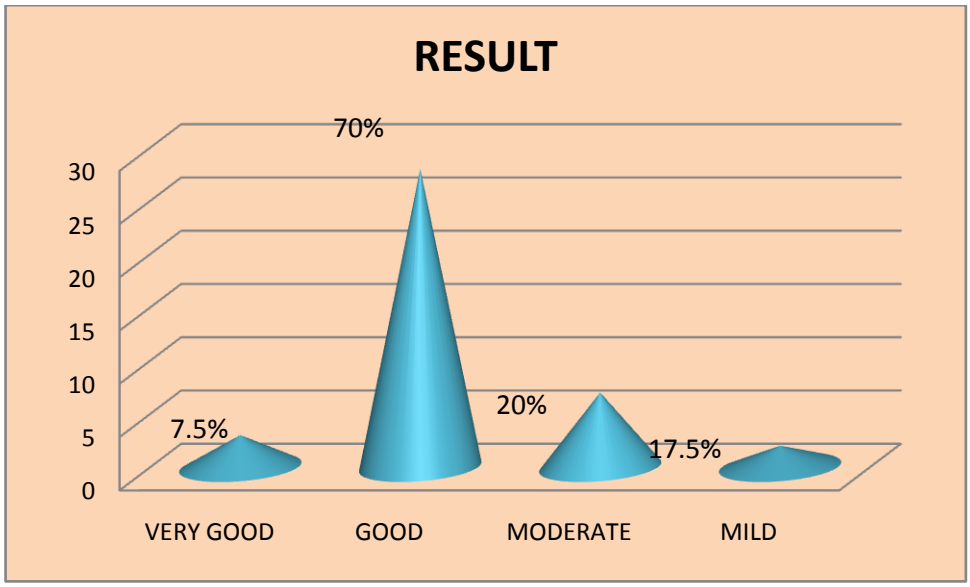
Observation:

In this study, Very Good improvement were observed in 10% of cases with varmam and 5% of cases without varmam group, Good improvement were observed in 85% of cases with varmam and 55% of caseswithout varmam, Moderate improvement observed in 35% of cases without varmam group and 5% of cases in both the groups shows Mild improvement.

Results

The trial drug *Rajaelathychooranam*(Internal) and *Nathaichooriennai* (External) were given to 40 patients for 48 days.

Sl. No	Results	No of Cases	Percentage
1	Very Good	3	7.5%
2	Good	28	70%
3	Moderate	7	17.5%
4	Mild	2	5%



Observation:

The trial drug Rajaelathychooranam(Internal) and *Nathaichooriennai* (External) were given to 40 patients for 48 days. Very Good improvement was observed in 3 patients (7.5%), Good improvement was observed in 28 patients (70%), moderate improvement in 7 patients (17.5%), and mild improvement in 2 (5%) cases.

Deference between Varmam and Withoutvarmam Group:

S Group	Sample size	Mean	Standard deviation	Significant
Varmam	20	17.215	14.296	0.0063
Without varmam	20	28.1065	12.433	0.10

There was differences in with varmam and without varmam group after treatment.

S NO	OP NO	NAME	AGE/ SEX	Hb		Total RBC		ESR				Total WBC	
								½ hour		1hour			
				BT	*AT*	BT	AT	BT	AT	BT	AT	BT	AT
1	H40776	MR.Dhandapani	62/M	15.6	14.8	4.5	5.0	20	20	40	40	7900	6800
2	9461	Mr.P.Babu	57/M	13.5	14	4.8	4.2	25	25	42	40	7000	7200
3	I64222	Mr.V.Mangai	43/F	13.7	13.6	4.5	4.5	8	8	16	16	7600	6300
4	8825	MMaheshwari	60/F	12.0	12.7	4.1	4.3	10	8	20	16	6400	6300
5	I69664	T.M.Kumar	58/M	14.6	14.9	5.1	5.2	10	10	20	20	6100	5800
6	I03771	Bakyamary	60/F	14.6	15	4.7	4.7	34	12	17	24	7500	7600
7	I80615	Indirani	50/F	13	13.5	4.5	4.6	15	10	30	31	7100	7000
8	8859	Vasanthi	64/F	11.1	11.9	3.9	4.2	24	34	48	70	9400	8300
9	I50208	P.V.sundarraj	54/M	12	13	4.3	4.4	25	28	30	30	8000	8100
10	I70853	Elamvazhuthi	61/M	14.8	15	5.2	5.2	2	2	4	4	6200	6400
11	H91187	Sugumar	37/M	15.7	15.5	5.2	5.2	2	2	4	4	6200	6400
12	G75398	Maheshwari	50/F	12.7	12.3	4.7	4.2	10	10	20	20	7700	7500
13	I61037	Sumathi	50/F	12.8	13	4.5	4.5	10	10	20	20	5500	5600
14	I69442	Mangayarthilagam	60/F	12.6	13	4.7	4.5	8	8	16	16	7200	7300
15	I88148	Iyyadurai	42/M	14.7	15.7	5.0	5.5	4	4	10	10	13000	11000
16	9557	Thulasigam	55/F	14	14.5	4.3	5.3	4	4	8	8	4000	5000
17	I85923	Kandhasami	43/M	14.6	15	5.8	5	6	6	14	14	10000	10000
18	I66909	Nagaraj	38/M	16.1	16	5.7	5.5	2	2	4	4	7800	7600
19	I70825	C.Nagarajan	60/M	14.5	15.1	5.1	5.3	4	14	10	30	8800	7400
20	8909	Meenatchi	57/F	12.9	13	4.9	4.5	10	10	22	22	10900	10000

S.NO	OP NO	NAME	AGE/ SEX	SGOT		SGPT		ALKALINE PHOPHATASE	
				BT	AT	BT	AT	BT	AT
1	C20391	K.Thirumaran	56/M	23	17	16	14	82	54
2	I41274	M.Bhavani	40/F	14	17.5	17	14.8	70	67
3	I39463	B.Jeeva	52/F	19	21	64	16	62	64
4	I37612	C.Mani	52/M	17	23	15	24	56	60
5	F043532	Govinthammal	38/F	15	17	21	21	105	105
6	H78671	Nirmala	53/F	17	18	17	14	72	74
7	I24657	B.PareshBehera	55/M	24	25	30	30	63	41
8	I68182	Rajasekar	36/M	17	20	29	25	69	69
9	G20673	N.Meerabegam	45/F	22	25.1	24	25.1	79	77
10	I69546	Muthulakshmi	52/F	13	19	13	10	74	78
11	H9339	Selvakumari	58/F	22	10.3	23	21	97	89
12	F54907	Thagappan	59/M	23	21	21	15	71	70
13	I5160	MUTHUKILI	40/F	13	22.5	19	20.5	69	78
14	G41863	R.Kannagi	48/F	15	15	19	20	99	100
15	I31482	R.K.Indrani	43/F	19	16	19	11	42	102
16	I48564	P.Sokkuvel	62/M	69	13	12	10	70	56
17	H37544	D.Kalavathy	64/M	15	17	13	16	77	87
18	I72321	K.Kumar	42/M	19	20	20	25	76	70
19	H63909	B.Srimathi	42/F	16.0	16.3	16.3	16.3	68	69
20	I7770	Amsavani	63/F	15	14	13	18	98	101

S. No	OP No	NAME	AGE/ SEX	URINE SUGER (F)		URINE SUGER (PP)		ALBUMIN		Epithelial cell		Pus cells	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	C20391	K.Thirumaran	56/M	nil	nil	nil	Nil	nil	nil	2-4	2-4	6-7	2-3
2	I41274	M.Bhavani	40/F	nil	nil	nil	Nil	nil	nil	2-4	3-5	2-4	3-5
3	I39463	B.Jeeva	52/F	nil	nil	nil	Nil	nil	nil	2-3	2-3	1-2	1-2
4	I37612	C.Mani	52/M	nil	nil	nil	Nil	nil	nil	2-4	2-4	2-3	3-3
5	F043532	Govinthammal	38/F	nil	nil	nil	Nil	nil	nil	6-7	3-4	2-4	1-2
6	H78671	Nirmala	53/F	nil	nil	nil	Nil	nil	nil	2-3	1-2	2-3	2-3
7	I24657	B.PareshBehera	55/M	nil	nil	nil	Nil	nil	nil	2-3	2-3	1-2	2-4
8	I68182	Rajasekar	36/M	nil	nil	nil	Nil	nil	nil	1-2	2-4	1-2	2-4
9	G20673	N.Meerabegam	45/F	nil	nil	nil	Nil	nil	nil	2-3	2-3	2-3	1-2
10	I69546	Muthulakshmi	52/F	nil	nil	nil	Nil	nil	nil	4-5	3-5	1-2	1-2
11	H9339	Selvakumari	58/F	nil	nil	nil	Nil	nil	nil	10-12	2-3	4-5	2-4
12	F54907	Thagappan	59/M	nil	nil	nil	Nil	nil	nil	2-4	3-5	2-3	2-3
13	I5160	MUTHUKILI	40/F	nil	nil	nil	Nil	nil	nil	1-2	1-2	6-8	1-2
14	G41863	R.Kannagi	48/F	nil	nil	nil	Nil	nil	nil	2-4	2-4	1-3	1-3
15	I31482	R.K.Indrani	43/F	nil	nil	nil	Nil	nil	nil	2-4	1-2	2-4	1-2
16	I48564	P.Sokkuvel	62/M	nil	nil	nil	Nil	nil	nil	2-4	6-7	4-6	2-3
17	H37544	D.Kalavathy	64/M	nil	nil	nil	Nil	nil	nil	3-5	2-5	2-4	2-4
18	I72321	K.Kumar	42/M	nil	nil	nil	Nil	nil	nil	1-2	1-2	2-4	1-2
19	H63909	B.Srimathi	42/F	nil	nil	nil	Nil	nil	nil	3-5	2-5	1-4	1-2
20	I7770	Amsavani	63/F	nil	nil	nil	Nil	nil	nil	3-5	2-5	1-4	1-2

S No	Op No	Name	Age/ Sex	Blood Glucose (F)		Blood Glucose		Urea		Creatinnine		Total Cholesteral	
				BT	***AT***	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**
1	H40776	Thandapani	62/M	107	102	109	110	22	21	1.0	0.9	195	188
2	9461	P.Babu	57/M	99	94	106	115	12	13	1.1	1.0	156	158
3	I64222	V.Mangai	43/F	110	108	113	110	16	14	0.8	0.8	179	140
4	8825	Maheshwari	60/F	97	98.8	109	110	24.8	20.7	0.99	0.87	160	169
5	I69664	T.M.Kumar	58/M	107	102	150	158	14	13	1.1	1.0	200	194
6	I03771	Bakyamary	60/F	102	100	103	130	13	13	1.0	1.0	178	178
7	I80615	Indirani	50/F	104	115	124	120	16	15	1.1	1.2	181	168
8	8859	Vasanthi	64/F	109	110	139	135	15	14	1.0	0.8	197	200
9	I50208	P.V.sundarraj	54/M	96	106	140	116	14	16	0.9	1.1	165	165
10	I70853	Elamvazhuthi	61/M	99	100	120	120	21	28	1.0	1.0	168	170
11	H91187	Sugumar	37/M	84	90	94	100	15	16	0.9	0.8	152	153
12	G75398	Maheshwari	50/F	110	109	125	120	19	19	1.0	0.9	251	256
13	I61037	Sumathi	50/F	93	90	101	120	28	20	1.2	1.0	208	200
14	I69442	Mangayar thilagam	60/F	98	100	120	125	17	18	0.8	1.0	183	170
15	I88148	Iyyadurai	42/M	95	94	135	145	26	17	1.2	1.0	231	175
16	9557	Thulasigam	55/F	89.9	89.9	110	120	29.8	30	1.09	1.0	168	170
17	I85923	Kandhasami	43/M	98	100	106	107	26	26	1.1	1.1	189	190
18	I66909	Nagaraj	38/M	87	90	133	129	32	32	1.0	1.0	230	212
19	I70825	C.Nagarajan	60/M	99	100	135	139	34	19	1.0	0.9	181	189
20	8909	Meenatchi	57/F	116	110	140	140	24.1	24	0.99	1	189	190

S NO	OP NO	NAME	AGE / SEX	Total bilirubin		calcium		Phosphorus		Uric acid	
				BT	***AT***	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**
1	H40776	Thandapani	62/M	0.7	0.5	8.9	8.2	3.6	3.4	4.4	4.8
2	9461	P.Babu	57/M	1.1	0.4	8.4	9.1	3.2	3.4	6.2	6.1
3	I64222	V.Mangai	43/F	0.3	0.3	9.1	9.0	2.7	3.3	3.7	3.7
4	8825	Maheshwari	60/F	1.2	1.2	8.4	9.0	3.95	4.54	4.5	4.2
5	I69664	T.M.Kumar	58/M	2.0	0.6	9.0	8.4	3.4	3.5	5.8	5.3
6	I03771	Bakyamary	60/F	0.7	0.7	9.2	9.3	3.6	3.7	4.7	4.8
7	I80615	Indirani	50/F	0.5	0.6	9.0	9.2	3.2	3.3	4.3	4.5
8	8859	Vasanthi	64/F	0.4	0.7	8.4	8.4	2.7	3.3	5.2	4.9
9	I50208	P.V.sundarraj	54/M	1.1	1.3	9.3	9.2	3.1	3.0	4.1	4.2
10	I70853	Elamvazhuthi	61/M	1.2	1.2	8.4	9.0	2.3	2.5	6.7	7
11	H91187	Sugumar	37/M	2.2	2.2	8.1	8.2	2.8	2.8	5.2	5.3
12	G75398	Maheshwari	50/F	0.5	0.4	9.2	9.1	3.4	3.9	6.1	5.8
13	I61037	Sumathi	50/F	0.5	0.6	9.2	9.3	4.3	4.3	5.6	5.5
14	I69442	Mangayarthilagam	60/F	0.4	0.4	9.5	9.6	3.0	3.0	3.0	3.2
15	I88148	Iyyadurai	42/M	0.3	0.4	9.7	8.6	3.8	3.7	9.0	8.4
16	9557	Thulasigam	55/F	0.8	0.8	9.5	10	3.21	3.2	6.3	6.4
17	I85923	Kandhasami	43/M	0.3	0.3	9.1	9.2	3.3	3.3	6.6	7
18	I66909	Nagaraj	38/M	0.4	0.4	9.1	9.3	3.2	3.4	5.0	5.0
19	I70825	C.Nagarajan	60/M	0.5	0.3	9.6	9.6	2.8	2.7	5.7	5.6
20	8909	Meenatchi	57/F	1.15	1.1	9.1	9	3.17	4	5.0	4.5

S NO	OP NO	NAME	AGE/ SEX	urine		Urine		Albumin		Epithelial cell		Pus cells	
				BT	***AT***	**BT**	**AT**	**BT**	**AT**	**BT**	**AT**	**BT**	**at**
1	H40776	Thandapani	62/M	nil	nil	nil	nil	nil	Nil	4-5	3-5	1-2	1-2
2	9461	P.Babu	57/M	nil	nil	nil	nil	nil	Nil	10-12	2-3	4-5	2-4
3	I64222	V.Mangai	43/F	nil	nil	nil	nil	nil	Nil	2-4	3-5	2-3	2-3
4	8825	Maheshwari	60/F	nil	nil	nil	nil	nil	Nil	1-2	1-2	6-8	1-2
5	I69664	T.M.Kumar	58/M	nil	nil	nil	nil	nil	Nil	2-4	2-4	1-3	1-3
6	I03771	Bakyamary	60/F	nil	nil	nil	nil	nil	Nil	2-4	1-2	2-4	1-2
7	I80615	Indirani	50/F	nil	nil	nil	nil	nil	Nil	2-4	2-4	6-7	2-3
8	8859	Vasanthi	64/F	nil	nil	nil	nil	nil	Nil	2-4	3-5	2-4	3-5
9	I50208	P.V.sundarraj	54/M	nil	nil	nil	nil	nil	Nil	2-3	2-3	1-2	1-2
10	I70853	Elamvazhuthi	61/M	nil	nil	nil	nil	nil	Nil	2-4	2-4	2-3	3-3
11	H91187	Sugumar	37/M	nil	nil	nil	nil	nil	Nil	6-7	3-4	2-4	1-2
12	G75398	Maheshwari	50/F	nil	nil	nil	nil	nil	nil	2-3	1-2	2-3	2-3
13	I61037	Sumathi	50/F	nil	nil	nil	nil	nil	nil	2-3	2-3	1-2	2-4
14	I69442	Mangayarthilagam	60/F	nil	nil	nil	nil	nil	nil	1-2	2-4	1-2	2-4
15	I88148	Iyyadurai	42/M	nil	nil	nil	nil	nil	nil	2-3	2-3	2-3	1-2
16	9557	Thulasigam	55/F	nil	nil	nil	nil	nil	nil	4-5	3-5	1-2	1-2
17	I85923	Kandhasami	43/M	nil	nil	nil	nil	nil	nil	10-12	2-3	4-5	2-4
18	I66909	Nagaraj	38/M	nil	nil	nil	nil	nil	nil	2-4	3-5	2-3	2-3
19	I70825	C.Nagarajan	60/M	nil	nil	nil	nil	nil	nil	1-2	1-2	6-8	1-2
20	8909	Meenatchi	57/F	nil	nil	nil	nil	nil	nil	1-2	2-4	1-2	2-4

S.NO	IP OP No	NAME	AGE/ SEX	Hb(gm/dl)		TOTAL RBC COUNT (million/cumm)			ESR (mm/hour)			TOTAL WBC COUNT	
				BT	AT	BT	AT	BT	AT	AT	AT	BT	AT
1	C20391	K.Thirumaran	56/M	15	14	5.6	5.2	2	4	2	4	5600	5800
2	I41274	M.Bhavani	40/F	11.5	11.5	4.7	4.9	22	46	15	30	8000	8200
3	I39463	B.Jeeva	52/F	13.9	13.`1	4.5	4.2	2	4	2	4	9400	9900
4	I37612	C.Mani	52/M	14.1	14.1	4.8	4.8	6	14	4	8	6100	6000
5	F043532	Govinthammal	38/F	9.9	10.3	4.1	4.1	12	24	20	42	10400	10600
6	H78671	Nirmala	53/F	12.6	12.8	4.5	4.7	12	26	20	42	5500	6700
7	I24657	B.PareshBehera	55/M	12	12.5	4.5	5.4	8	16	8	16	7400	8600
8	I68182	Rajasekar	36/M	15.3	15.1	5.7	5.6	8	16	8	16	6900	8100
9	G20673	N.Meerabegam	45/F	12.8	13	4.5	4.5	12	26	20	42	6400	6600
10	I69546	Muthulakshmi	52/F	14.5	14.5	5.1	5.1	12	24	20	42	7700	6100
11	H9339	Selvakumari	58/F	14.5	12	4.1	4.2	30	60	30	60	8900	9000
12	F54907	Thagappan	59/M	13.9	14	4.7	4.7	8	16	8	16	7300	8000
13	I5160	Muthukili	40/F	11.6	11.5	4.5	4.4	4	8	4	8	7300	5700
14	G41863	R.Kannagi	48/F	11.9	11.7	4.5	4.4	20	46	16	34	4400	5200
15	I31482	R.K.Indrani	43/F	10.2	10.3	4.3	4.2	16	32	56	112	4200	5300
16	I48564	P.Sokkuvel	62/M	14.5	14	5	4.8	20	44	10	20	8700	8700
17	H37544	D.Kalavathy	64/M	14.8	14.7	5.3	5.3	8	16	16	16	6600	6000
18	I72321	K.Kumar	42/M	14.5	12	4.1	4.2	30	60	30	60	8900	9000
19	H63909	B.Srimathi	42/F	13.2	13	4.3	4.5	6	12	6	12	7600	7000
20	I7770	Amsavani	63/F	13.3	13	4.4	4.3	8	16	8	16	6100	6100

S.NO	IP/OP NO	NAME	AGE/ SEX	ASO		CRP		RA FACTOR	
				BT	AT	BT	AT	BT	AT
1	H40776	MR.Dhandapani	62/M	-	-	-	-	-	-
2	9461	Mr.P.Babu	57/M	-	-	-	-	-	-
3	I64222	Mr.V.Mangai	43/F	-	-	-	-	-	-
4	8825	MMaheshwari	60/F	-	-	-	-	-	-
5	I69664	T.M.Kumar	58/M	-	-	+	+	-	-
6	I03771	Bakyamary	60/F	-	-	+	+	-	-
7	I80615	Indirani	50/F	-	-	+	+	-	-
8	8859	Vasanthi	64/F	-	-	-	-	-	-
9	I50208	P.V.sundarraj	54/M	-	-	-	-	-	-
10	I70853	Elamvazhuthi	61/M	-	-	-	-	-	-
11	H91187	Sugumar	37/M	-	-	-	-	-	-
12	G75398	Maheshwari	50/F	-	-	+	+	-	-
13	I61037	Sumathi	50/F	-	-	+	+	-	-
14	I69442	Mangayarthilagam	60/F	-	-	+	+	-	-
15	I88148	Iyyadurai	42/M	-	-	-	-	-	-
16	9557	Thulasigam	55/F	-	-	-	-	-	-
17	I85923	Kandhasami	43/M	-	-	-	-	-	-
18	I66909	Nagaraj	38/M	-	-	-	-	-	-
19	I70825	C.Nagarajan	60/M	-	-	-	-	-	-
20	8909	Meenatchi	57/F	-	-	-	-	-	-

S.NO	IP/OP NO	NAME	AGE/ SEX	ASO		CRP		RAFACTOR	
				BT	AT	BT	AT	BT	AT
2	I41274	M.Bhavani	40/F	-	-	-	-	-	-
3	I39463	B.Jeeva	52/F	-	-	-	-	-	-
4	I37612	C.Mani	52/M	-	-	-	-	-	-
5	F043532	Govinthammal	38/F	-	-	-	-	-	-
6	H78671	Nirmala	53/F	-	-	-	-	-	-
7	I24657	B.PareshBehera	55/M	-	-	+	+	-	-
8	I68182	Rajasekar	36/M	-	-	+	+	-	-
9	G20673	N.Meerabegam	45/F	-	-	+		-	-
10	I69546	Muthulakshmi	52/F	-	-	-	-	-	-
11	H9339	Selvakumari	58/F	-	-	-	-	-	-
12	F54907	Thagappan	59/M	-	-	-	-	-	-
13	I5160	MUTHUKILI	40/F	-	-	-	-	-	-
14	G41863	R.Kannagi	48/F	-	-	+	+	-	-
15	I31482	R.K.Indrani	43/F	-	-	+	+	-	-
16	I48564	P.Sokkuvel	62/M	-	-	+	+	-	-
17	H37544	D.Kalavathy	64/M	-	-	+	+	-	-
18	I72321	K.Kumar	42/M	-	-	-	-	-	-
19	H63909	B.Srimathi	42/F	-	-	-	-	-	-
20	I7770	Amsavani	63/F	-	-	-	-	-	-

S.NO	OP NO	NAME	AGE/ SEX	SGOT		SGPT		ALKALINE PHOPHATASE	
				BT	AT	BT	AT	BT	AT
1	H40776	MR.Dhandapani	62/M	23	17	16	14	82	54
2	9461	Mr.P.Babu	57/M	14	17.5	17	14.8	70	67
3	I64222	Mr.V.Mangai	43/F	19	21	64	16	62	64
4	8825	MMaheshwari	60/F	17	23	15	24	56	60
5	I69664	T.M.Kumar	58/M	15	17	21	21	105	105
6	I03771	Bakyamary	60/F	17	18	17	14	72	74
7	I80615	Indirani	50/F	24	25	30	30	63	41
8	8859	Vasanthi	64/F	17	20	29	25	69	69
9	I50208	P.V.sundarraj	54/M	22	25.1	24	25.1	79	77
10	I70853	Elamvazhuthi	61/M	13	19	13	10	74	78
11	H91187	Sugumar	37/M	22	10.3	23	21	97	89
12	G75398	Maheshwari	50/F	23	21	21	15	71	70
13	I61037	Sumathi	50/F	13	22.5	19	20.5	69	78
14	I69442	Mangayarthilagam	60/F	15	15	19	20	99	100
15	I88148	Iyyadurai	42/M	19	16	19	11	42	102
16	9557	Thulasigam	55/F	69	13	12	10	70	56
17	I85923	Kandhasami	43/M	15	17	13	16	77	87
18	I66909	Nagaraj	38/M	19	20	20	25	76	70
19	I70825	C.Nagarajan	60/M	16.0	16.3	16.3	16.3	68	69
20	8909	Meenatchi	57/F	15	14	13	18	98	101

STATISTICAL ANALYSIS

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired‘t’ test was performed for determining the significance between before and after treatment.

Paired Sample Statistics (SPADI) Score Before Treatment and After Treatment for Group A (Trial medicine along with Varmam)

Variable	Obs	Mean±SD	t Value	p Value
Before treatment	20	80.0295±5.189	T=20.921	p>0.0063
After treatment	20	17.215±14.296		

The mean± standard deviation of SPADI score before and after treatment were 80.0295 ±5.189 and 17.215 ±14.296 respectively which is statistically significant (t=20.921, p=0.0063).

Paired Sample Statistics (SPADI) Score Before Treatment and After Treatment For Group B (Trial medicine only)

Variable	Obs	Mean±SD	t Value	p Value
Before treatment	20	79.824±5.861	T=17.831	p>0.10
After treatment	20	28.1065±12.433		

The mean± standard deviation of SPADI score at before and after treatment were 79.824 ±5.861and 28.1065±12.433respectively. (t=17.831, p=0.10).

Difference between group –A and group - B

Sco Score	Sample size	Mean	Standard deviation	Significant
Group -A	20	17.215	5.189	0.0063
AAA Group - B	20	28.1065	12.433	0.10

The result of group A (with varmam) is significant than the group B (without Varma)

DISCUSSION

Periarthritis (*Kumbavatham*) is one of the Painfull and Disabiling disorders of unclear cause in shoulder capsule the connective tissue surrounding the glenohumeral joint of the shoulder. People who suffer from periarthritis usually experience severe pain and sleep disturbances, they have extreme difficulty concentrating, working or performing daily activities for extend period of time. The condition tends to be self limiting and usually resolves over time without surgery.

The trial drugs were prepared in Gunapadam lab of National Institute of Siddha after the authentication of the raw drugs from Dr. D. Aravind M.D(S) Assistant professor, Dept. of Botany, National institute of siddha. The trail drug was prepared by standard operating procedure as mentioned in the Protocol.

The Bio chemical analysis was done at the biochemistry lab of NIS and the results were documented. The Bio-chemical analysis of had shown the presence of Chloride, Phosphate, Carbonate, Calcium, Potassium, Nitrite, Iron, Tannic acid, starch, sulphate and Alkaloids.

The short term toxicity study in animal models carried out as per WHO guideline, there was no treatment- related death or signs of toxicity developed in albino rats at dosage levels of 2000mg / kg body weight throughout the study period. Further, no gross pathological changes have been seen in the internal organs of both control and treated groups. Thus, the LD_{50} value was found to be greater than 2000mg / kg body weight, and this provides direct relevance for protecting human and animal health.

To ensure the safety of Rajaelathy Chooranam, Long term Toxicity Study was also carried out as per WHO guideline, except for hyperactivity at the time of drug administration, no other signs of toxicity were noted. After blood collection, all the animals were euthanized for gross pathological examinations of all major internal organs. The blood samples were sent to a lab for hematological and biochemical analysis. The organs were weighed and preserved in 10% buffered formalin solution before sending for histopathological study. All the reports were statistically analyzed.

There was no Significant changes in food intake of the test group animals before and after the administration of trial drug when compared with control group during the

study period. The haemopoietic system serves as an important target for toxic chemicals and is a sensitive index for pathological conditions both in humans and animals. In Haematological parameters, it had been observed normal in high dose level, Transaminases (SGOT and SGPT) are good indicators of liver function and biomarkers to predict the possible toxicity of drugs. Any elevation pertaining to the enzymes indicate their out flow in to the blood stream due to damage in liver parenchymal cells, there was normal limits in SGOT and SGPT in high dose treated animals, when compared to control group. In the present study, there was no treatment-related abnormality in renal functions at all the animals. The therapeutic dose of *Rajaelathy Chooranam* is 2gm/day for the human uses mentioned in Siddha text. This dose was safest dose in humans form the above studies.

In histopathologicalstudy**,** organs such as brain, heart, kidney, liver, lungs, spleen and stomach were taken. In organs of Control group, no abnormality was detected during the study period.

The Literature Review reveals that there was no such research has been done on *Rajaelathy Chooranam.* As an initial step, in this present study, a part of standardization of this drug and its safety has been confirmed through necessary analysis and Short term & Long term Toxicity studies as per WHO guidelines.

The clinical study was conducted with a well-defined protocol and a proper proforma after the approval of Institutional Ethical Committee.

For this dissertation study, 40 patients were selected and Patients were treated in the OP/IP department of *Sirappu Maruthuvam,* in Ayothidoss Pandithar Hospital - National Institute of Siddha, Tambaram Sanatorium, Chennai –600 047.

Based on various criteria, the data were collected and tabulated. The criteria were family history, sex predominance, age distribution, occupation, dietary habits and incidence of the disease with reference to thinai, seasonal variation, clinical manifestations and assessment of the improvement in the prognosis of the disease with the trial drug.

In Siddha System, it is necessary to bring the vitiated humours to equilibrium. Hence before the treatment *Meganatha kuzhigai-2* pills with warm water was given for *Viresanam* (Purgation) in the early morning to normalize the vitiated humours. During the treatment, the patients were advised to follow *pathiyam* (Dietary regimen).

Internal Drug : *Rajaelathy chooranam*- 1gm two times per day with water.
External Drug : *Nathaichoori ennai* for external application.
Duration of Drug : 48 days

40 patients of both genders were recruited for this study. Among the 40 patients, 22 (55%) patients were females and 18(45%) patients were males. Generally this condition is more common in females, this study also concludes the same.

Among 40 patients, 17 (42.5%) patients between 36-50 and years, 23 (57.5%) patients between 51 and 65 years. *Kumbavaatham* commonly occurs between the age of 20-60 years.

The majority of patients in this study were Homemakers 18(45%), Cooly 6(15%) and Driver 5 (12.5%). Businessman 2 (5%), Carpenter 3(7.5%), Clerical 4(10%), Baker 1 (2.5%) Electrician 1 (2.5%).

The majority of patients in this study were Non vegetarian (95%) remaining (5%) patients were vegetarian.

100% of the patients showed negative family history

In this present study, among 40 patients considerable numbers of patients were reported from *Neithal* (30patients) and *Marutham* (10 patients)

All the 40 patients were in pitha kaalam (34-66yrs)

Among40 patients 23 patients (57.5%) were affected in durations of 0-3months, 15(37.5%) patients were affected by the illness from 4-6 months, 2 (5%) were affected by the illness from 7-9 months.

Out of 40 patients all (100%) had clinical features of pain and restriction of movements, radiating pain in affected arm, difficulty in Abduction and External rotation and Tenderness was noted in 30 (75%) patients, Local heat was noted in 7(17.5%) patients.

In this study, Very Good improvement were observed in 10% of cases with Varmam and 5% of cases without Varmam group, Good improvement were observed in 85% of cases with Varmam and 55% of cases without Varmam, Moderate improvement

observed in 35% of cases without Varmam group and 5% of cases in both the groups shows Mild improvement. The result of group A (with Varmam) is significant than group B (without Varmam). So the Varmam therapy is beneficial in *Kumbavaatham* patients along with trial medicine.

The outcome of this study was clinically observed by SPADI Score, which showed encouraging results of very good improvement in 3 patients (7.5%), good improvement in 28(70%) patients, moderate improvement in 7 Patients (17.5%) and mild improvement in 2 case (5%).

Laboratory investigations were done for all the cases before and after treatment. There were no significant variations in hepatic, renal and other parameters before and after treatment

In this study, no adverse events were observed during the course of the treatment. At the time of discharge, all the patients were advised to attend Out-Patient Department of Sirappu Maruthuvam of NIS for further follow-up treatment.

SUMMARY

The disease *Kumbavaatham* was taken for the clinical study with *Rajaelathy Chooranam* as internal medicine and *Nathai choori Ennai* as external application. For the clinical study, 40 cases were selected based on the approved protocol.

This study has been approved by **IEC of NIS [Date of IEC Approval & its number: NIS/IEC/9-2014-15/15-26.08.2015].** Animal studies were carried out after obtaining approval from the Institutional Animal Ethical Committee (IAEC) and the trial was registered in Clinical Trial Registry of India (CTRI/2017/05/008593). Hence the study is safely executed on patients and there was no adverse drug reactions noted during the study period.

The toxicological evaluations were conducted as per WHO guidelines for safety evaluation of *Rajaelathy Chooranam*. In short term and long term toxicity study, no signs of toxicity and mortality were observed throughout the study period. In organs of Control group, no abnormality was detected. The normal histological structure present in test group of animals.

In clinical trial out of the 40 cases, 20 cases were treated with trial medicine along with varmam theraphy, remaining 20 cases were treated with trial medicine only in Ayothidoss Pandithar Hospital of National Institute of Siddha, Chennai-47. The detailed study on *Rajaelathy chooranam* with reference to its aetiology, pathogenesis, investigations, clinical features, diagnosis and treatment with trial drugs were done.

The results were observed by SPADI score. Among the cases treated, 3 (7.5%)cases had Very Good improvement, 28 (70%)cases had shown Good improvement, 7 (17.5%) cases had Moderate improvement and 2 (5%)cases had shown Mild improvement. The result of group A (with varmam) is significant than group B (without varmam). So the varmam therapy is beneficial in *kumbavaatham* patients along with trial medicine.

CONCLUSION

The present clinical study confirms the efficacy of the trial drugs *Rajaelathy chooranam* (Internally) and *Nathai choori Ennai (Externally)* with and without Varmam therapy. It is also found that the trial medicine along with Varmam therapy shows better results when compared with the group B which took the trial medicine only in the treatment of *Kumbavatham*

The Short term and Long term toxicity studies did not show any toxic effects in the animal models.

The quantitative outcome of SPADI score shows significant reduction in the symptom of Kumbavaatham. There is Very Good improvement was observed in 3 patients (7.5%), Good improvement was observed in 28 patients (70%), moderate improvement in 7 patients (17.5%), and mild improvement in 2 (5%) cases.

The result of group A (with varmam) is significant than group B (without varmam). So the varmam therapy is beneficial in *Kumbavaatham* patients along with trial medicine.

The clinical trial conducted in selected patients was satisfactory and the results were encouraging. However a study with large number of patients is required to find out the ideal dose response. The cost of the trail medicines is low. These drugs are easily available and the dosage is also convenient. These drugs may be taken up for further exploratory randomised clinical trials to confirm the efficacy.

NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND CLINICAL STUDY OF SIDDHA DRUG *"RAJAELATHY CHOORNAM "*(INTERNAL) AND *"NATHAICHOORI ENNAI"* (EXTERNAL) IN THE TREATMENT OF *"KUMBAVATHAM "* (PERIARTHRITIS SHOULDER).

Principal Investigator: Dr.C.Shyfa.

FORM I - SCREENING & SELECTION PROFORMA

1. SERIAL NO: **2. OP /IP NO:**
3. NAME: **4. AGE/GENDER:**
5. OCCUPATION: **6. INCOME:**

INCLUSION CRITERIA

- Age: 20-65 YES\ NO
- Sex:Both male and female M \ F
- Pain and stiffness in shoulder region. YES\NO
- Exacerbation of pain on movement YES\ NO
- Restricted movements of shoulder joint (abduction and external rotation) YES\ NO
- With or without pain radiating to upper arm YES\ NO
- Patient willingn undergo radiological investigation and give blood samples for laboratory investigation YES\ NO
- Patient willing to sign the informed consent stating that he/she will consciously stick to the treatment but can opt out of the trial of his/her own conscious discretion. YES\ NO

EXCLUSION CRITERIA

- H/O Diabetes Mellitus YES\ NO
- H/O Cardiac disease YES\ NO
- H/O Septic arthritis YES\ NO
- H/O Gonococcal arthritis YES\ NO
- H/O Pregnancy and lactation YES\ NO
- H/O Malignant hypertension YES\ NO
- H/O Any fracture or dislocation of shoulder joint YES\ NO
- H/O Cervical spondylosis YES\ NO
- H/O Any other chronic illness YES\ NO

ADMITTED TO TRAIL

YES ☐ NO ☐
If Yes, OPD ☐ IPD ☐
Serial NO: ☐

Date:
Station:
Signature of the Investigator:
Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600 047.

POST - GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND CLINICAL STUDY OF SIDDHA DRUG ***"RAJAELATY CHOORNAM"*** (INTERNAL) AND **"*NATHAICHOORI ENNAI"*** (EXTERNAL) IN THE TREATMENT OF ***KUMBAVATHAM*** (Periarthritis Shoulder).

PRINCIPAL INVESTIGATOR**:Dr C. SHYFA**

FORM II – HISTORY TAKING FORM

STUDY NO : **OP / IP NO:**

NAME: **AGE/GENDER:**

ADDRESS: **CONTACT NO:**

RELIGION: H / M / C / O

OCCUPATION: **INCOME:**

MARRITAL STATUS: **MARRIED** ☐ **UNMARRIED** ☐

DATE OF INITIAL ASSESSMENT:

COMPLAINTS & DURATION:

PERSONAL HISTORY:

PERSONAL HABITS	YES	NO	IF YES SPECIFY DURATION	AMOUNT/Qty
Smoking				
Tobacco Chewing				
Alcohol				
Narcotic Drug Addiction				

HISTORY OF PREVIOUS ILLNESS AND TREATMENT TAKEN :

FAMILY HISTORY :

Whether this problem runs in family? 1. Yes ☐ 2.No ☐

If yes, mention the relationship of affected person(s)

1._____ 2._____

DIETARY HABIT: 1.Vegetarian ☐ 2.Non-vegetarian ☐

MENSTURAL HISTORY AND OBSTETRIC HISTORY:

FORM II a

GENERAL EXAMINATION:

1. Body weight [Kg] :
2. Height [cms] :
3. Body Temperature [^{0}F] :
4. Blood Pressure (mm/Hg) :
5. Pulse Rate /min. :
6. Heart Rate / min. :
7. Respiratory Rate /min. :

		Yes	**No**
8.	Pallor :	☐	☐
9.	Jaundice :	☐	☐
10.	Clubbing :	☐	☐
11.	Cyanosis :	☐	☐
12.	Pedal Oedema :	☐	☐
13.	Lymphadenopathy :	☐	☐
14.	Jugular venous pulsation :	☐	☐

VITAL ORGANS EXAMINATION:	**Normal**	**Abnormal**
1. Heart	☐	☐
2. Lungs	☐	☐
3. Brain	☐	☐
4. Liver	☐	☐
5. Kidney	☐	☐
6. Spleen	☐	☐
7. Stomach	☐	☐

SYSTEMIC EXAMINATION:	**Normal**	**Abnormal**
1. Cardio-vascular system	☐	☐
2. Respiratory system	☐	☐
3. Gastro intestinal system	☐	☐

4. Central nervous system ☐ ☐
5. Uro-genital system ☐ ☐
6. Endocrine system ☐ ☐

SIDDHA SYSTEM OF EXAMINATION :

1. THEGI (TYPE OF BODY CONSTITUTION):

1. Vaathaudal 3. Kabaudal

2. Pithaudal4. Thonthaudal

2. NILAM (LAND WHERE THE PATIENT LIVED MOST):

1. Kurinji 3. Paalai

2. Mullai4. Neithal

5. Marutham

3. KAALAM:

1. Kaarkaalam4. Pinpanikaalam

2. Koothirkaalam 5. Ilavenilkaalam

3. Munpanikaalam 6. Muthuvenilkaalam

4. GUNAM:

1. Sathuvam 2. Rasogunam

3. Thamogunam

5. PORIPULANGAL (SENSORY ORGANS):

	1st day	**8th day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**
Mei (skin)								
Vaai(tongue)								
Kan (eye)								
Mooku(nose)								
Sevi (ear)								

6. KANMENDRIYAM (MOTOR ORGANS):

	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Kai(upper limb)								
Kaal(lower limb)								
Vaai(speech)								
Eruvai(excretory organ)								
Karuvai(reproductive organs)								

7. KOSANGAL (SHEATH):

	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
AnnamayaKosam								
Pranamayakosam								
Manomayakosam								
Vignanamayakosam								
Aananthamayakosam								

8.UYIR THATHUKKAL (THREE HUMOURS):

A. VALI

	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Praanan								
Abaanan								
Viyaanan								

Udhaanan								
Samaanan								
Naagan								
Koorman								
Kirukaran								
Devathathan								
Dhananjeyan								

B) AZHAL

	1st day	**8th Day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**
Analakam								
Prasakam								
Ranjakam								
Aalosakam								
Saathakam								

C. IYAM:

	1st day	**8th day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**
Avalambagam								
Kilethagam								
Pothagam								

Tharpagam								
Santhigam								

9.SEVEN UDAL DHATHUS: (7 SOMATIC COMPONENTS)

	1st day	**8th day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**
Saaram								
Senneer								
Oon								
Kozhuppu								
Enbu								
Moolai								
Sukkilam /								
Suronitham								

ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

1st Day	**8th day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**

II. SPARISAM:

1st Day	**8th Day**	**15th Day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**

III. NAA:[TONGUE]

1st Day	8th Day	15th Day	22nd Day	29th Day	36th Day	43rd Day	49th Day

VI.NIRAM: [COMPLEXION]

1. Vaatham ☐ 3. Kabam ☐

2. Pitham ☐

V.MOZHI: [VOICE]

1. High Pitched ☐ 2. Low Pitched ☐

3. Medium Pitched ☐

VI.VIZHI: [EYES]

1st Day	8th Day	15th Day	22nd Day	29th Day	36th Day	43rd Day	49th Day

VII. MALAM: [BOWEL HABITS / STOOLS]

	Before treatment	After treatment
Niram		
Irugal		
Ilagal		
Others		

VIII. MOOTHIRAM [URINE EXAMINATION]

Neerkkuri	Before treatment	After treatment
Niram		
Manam		
Edai		
Nurai		
Enjal		

NEIKURI	Before treatment	After treatment
Aravu (Serpentine fashion)		
Aazhi (Annular/Ringed fashion)		
Muthu (Pearl beaded fashion)		
Kalappu (Mixed fashion)		
Other fashion		

CLINICAL EXAMINATION:

CLINICAL SYMPTOMS:

AFFECTED SHOULDER : Right ☐ Left ☐ Both ☐

PAIN AND STIFFNESS IN SHOULDER JOINT : Mild ☐ Moderate ☐ Severe ☐

ONSET : Sudden ☐ Gradual ☐

EARLY MORNING STIFFNESS **:Present** or **Absent**

AGGRAVATING FACTOR (movements) : **Yes** or **No**

RELIEVING FACTORS :

TENDERNESS :

RESTRICTION OF MOVEMENTS :

CLINICAL EXAMINATION OF SHOULDER JOINT

I.INSPECTION:

	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Attitude:								
Swelling								
Muscle wasting								
Deformity								

II.PALPATION:

	1st day	8th day	15th day	22th day	29th day	36th day	43rdday	49th day
Tenderness								
Local heat								

III. MOVEMENTS of shoulder joint

	1st day	8th day	15th day	22nd day	29th day	36rd day	43rd day	49th day
Flexion								
Extension								
Abduction								
Adduction								
Internal rotation								
External rotation								

Shoulder Pain and Disability Index (SPADI)

Please place a mark on the line that best represents your experience during the last week attributable to your shoulder problem.

PAIN SCALE

How severe is your pain?

Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable

At its worst?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
When lying on the involved side?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Reaching for something on a high shelf?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Touching the back of your neck?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Pushing with the involved arm?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

DISABILITY SCALE :

How much difficulty do you have?

Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help.

Washing your hair?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Washing your back?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Putting on an undershirt or jumper?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Putting on a shirt that buttons down the front?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Putting on your pants?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Placing an object on a high shelf?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Carrying a heavy object of 10 pounds (4.5 kilograms)	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Removing something from your back pocket?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

RESULTS OF PAIN SCALE :

	1st day	**8th day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**
At its worst?								
When lying on the involved side?								
Reaching for some thing on a high shelf?								
Touching the back of your neck?								
Pushing with the involved arm?								
Total								

RESULTS OF DISABILITY SCALE :

	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Washing your hair?								
Washing your back?								
Putting on an under skirt or a jumper?								
Putting on a shirt that buttons down the front?								
Putting on your pants?								
Placing an object on a high shelf?								
Carrying a heavy object of 10 pounds (4.5 kilograms)								
Removing something from your back pocket?								
Total								

TOTAL RESULTS

	1st Day	8th Day	15th Day	22th Day	29th Day	36th Day	43rd Day	49th Day
Total Score								

NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

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FORM-V–INFORMATION SHEET

Name of Principal Investigator :Dr .C.Shyfa
Name of the institute : National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL:

I, Dr.C.Shyfa Studying as M.D(Siddha) at National Institute of Siddha, Tambaram Sanatorium is doing a trial on the study of kumbavatham (periarthritic shoulder). Periarthritisis a most common persistent joint disease, occurring throughout the world. In this regard, I am in a need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine Rajaelathy choornam (Internal medicine) Twice a Day with hot water for 48 days) and nathai choori ennai (External medicine) along with varmam therapy for patients who are wilin to stay in IPD.Treatment will be provided to you assuring that you will not be definitely hurt in any course of treatment.

The information I am collecting in this study will remain between you and the principal investigator (myself).

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr.C.Shyfa, PG Scholar cum principal investigator of this study,attached to National Institute of Siddha,Chennai-47. You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, for rights and participation in the study.

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Name of Principal Investigator: Dr.C.Shyfa

FORM-VI – CONSENT FORM

*"**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.***

***I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care**".*

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant

In case of illiterate participant

*"**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm individual has given consent freely**."*

Date:

Signature of a witness
(Selected by the participant bearing no connection with the survey team)

Left thumb Impressionof the Participant

FORM –VI ஒப்புதல் படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் கும்பவாதம் என்னும் நோயின் ஆய்வைக் குறித்த அனைத்துவிபரங்களையும் நோயாளிக்குப்புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: **கையொப்பம்:**

இடம்: **பெயர்:**

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும்மருத்துவ வழிமுறை பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும்மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால்விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது, எப்பொழுது வேண்டுமானாலும்இந்த ஆய்விலிருந்து என்னைவிடுவித்து கொள்ளும் உரிமையைத் தெரிந்திருக்கின்றேன்.

நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டுகும்பவாதம் நோய்க்கான ராஜஏலாதி சூரணம் (உள் மருந்து) மற்றும்நத்தைச்சூரி எண்ணெய்(வெளி மருந்து) மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: **கையொப்பம்:**

இடம்: **பெயர்:**

சாட்சிக்காரர் கையொப்பம்:

பெயர்:

உறவுமுறை:

விரிவுரையாளர் கையொப்பம்: **துறைத்தலைவர் கையொப்பம்**

NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

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Name of Principal Investigator: Dr.C.Shyfa

FORM VII -WITHDRAWAL FORM

1. SERIAL NO OF THE CASE:

2. OP / IP NO:

3. NAME:

4. AGE:

5. GENDER:

6. DATE OF TRIAL COMMENCEMENT:

7. DATE OF WITHDRAWAL FROM TRIAL:

8. REASONS FOR WITHDRAWAL:

Long absence at reporting:	Yes/ No
Irregular treatment:	Yes/ No
Shift of locality:	Yes/No
Increase in severity of symptoms:	Yes/No
Development of severe adverse drug reactions:	Yes/No
Development of adverse event:	Yes/No

(If YES, give the details of adverse reaction in Form VII -B – Adverse Reaction Form / Pharmaco Vigilance Form)

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA
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DEPARTMENT OF SIRAPPU MARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"RAJAELATHI CHOORNAM"*** (INTERNAL) AND **"NATHAICHOORI ENNAI"** (EXTERNAL) IN THE TREATMENT OF **"**KUMBAVATHAM*"*WITH AND WITHOUT YOGAM.

Name of Principal Investigator: Dr.C.Shyfa

FORM VII - A – ADVERSE REACTION FORM / PHARMACO VIGILANCE FORM

SERIAL NO:

OP/IP NO:

NAME: **AGE:** **GENDER:**

DATE OF TRIAL COMMENCEMENT:

DATE OF THE ADVERSE REACTION OCCUR:

DESCRIPTION OF ADVERSE REACTION:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA
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DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND CLINICAL STUDY OF SIDDHA DRUG *"*RAJAELATHICHOORNAM*"* (INTERNAL) AND *"*NATHAICHOORI ENNAI*"* (EXTERNAL) IN THE TREATMENT OF *"*KUMBAVATHAM*"* (Periarthritic shoulder).

Principal Investigator: Dr.C.Shyfa

1.SERIAL NO: **2. OP /IP NO:**
3. NAME: **4. AGE/GENDER:**

FORM-III - LABORATORY INVESTIGATIONS

BLOOD INVESTIGATIONS		**NORMAL VALUES**	**BEFORE TREATMENT**	**AFTER TREATMENT**
Hb(gm/dl)		**M:13-18** **W:11-16**		
T.RBC(millions cells /Cu.mm)		**M:4.5-6.5** **W:3.5-5.5**		
ESR (mm)	**½ hr.**	**-**		
	1 hr.	**M:0-10** **W:0-20**		
T.WBC (Cells /Cu.mm)		**4000-11000**		
Differential Count (%)	**Polymorphs**	**40-75**		
	Lymphocytes	**20-35**		
	Monocytes	**2-10**		
	Eosinophils	**1-6**		
	Basophils	**0-1**		

BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TREATMENT	AFTER TREATMENT
Blood glucose (mg/dl)	Fasting	70-110		
	PP	80-140		
Lipid profile (mg/dl)	Serum cholesterol	150-200		
	HDL	30-60		
	LDL	Up to 130		
	VLDL	40		
	TGL	Up to 160		
RFT (mg/dl)	Blood urea	16-50		
	Serum creatinine	0.6-1.2		
LFT (mg/dl)	Total bilirubin	0.2-1.2		
	Direct bilirubin	0.1-0.2		
	Indirect bilirubin	0.2-0.7		
	Total protein	6-8		
	Serum Albumin	3.5-5.5		
	Serum globulin	2-3.5		
	SGOT (IU/L)	0-40		
	SGPT (IU/L)	0-35		
	Alkaline phosphatase	80-290		
	Serum calcium	9-11		
	Serum phosphorus	2-5		
	Serum Uric acid	M:3-9 W: 2.5-7.5		
CRP				
ASO titre				
RA factor				

B.URINE INVESTIGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar (Fasting) **(PP)**		
Deposits		
Bile salts		
Bile pigments		

C.RADIOLOGICAL EXAMINATIONS

X- Ray: SHOULDER JOINT

1. **Antero posterior**

Date:
Station:
Signature of the Investigator:
Signature of the Lecturer: **Signature of the HOD**

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Principal Investigator: Dr.C.Shyfa

FORM -VII DIETARY ADVICE FORM

சேர்க்க கூடிய உணவுகள்	தவிர்க்க வேண்டியவைகள்
காய்கள்(Vegetables): கத்தரிப்பிஞ்சு (Unripe brinjal) முருங்கைப்பிஞ்சு(Unripe drumstick) அவரைப்பிஞ்சு (Unripe Dolichos bean) **கீரைகள்(Greens):** பொன்னாங்கண்ணி (Sessile plant [*Alternantherasessilis*]) மூக்கிரட்டை (Hog weed [*Boerhaaviadiffusa*]) தூதுவேளை (Climbing brinjal [*Solanum trilobatum*]) முருங்கைக்கீரை (Leaves of Drumstick [*Moringaoleifera*]) கறிவேப்பிலை (Curry leaf [*Murrayakoenigii*]) முடக்கறுத்தான் (Winter cherry [*Cardiospermumhalicacabum*]) அறுகீரை (*Amaranthustristis*) கரிசாலை (trailing eclipta [Eclipta prostrate]) **பழங்கள்(Fruits):** மாதுளை (Pomegranate) ஆப்பிள் (Apple) பப்பாளி (Papaya) ஆரஞ்சு (Orange) பேரீச்சை (Dates) அத்தி (Fig) நாவல் (Jambul [*Syzygiumcumini*]) **அசைவம் (Non-vegetarian diet):** வெள்ளாட்டுக்கறி (Meat) காடை (Quail) , சிறு இறால்மீன் (Prawn)	சுரை (Bottle gourd) பூசணி (Pumpkin) வெள்ளரிக்காய் (Cucumber) புடலை (Snake gourd) பீர்க்கு (Ridged gourd) உளுந்து (Black gram) மொச்சை (Indian butter Bean) காராமணி (Cow gram) கொள்ளு (Horse gram) கடுகு (Mustard) எண்ணெய் (Gingelly oil) புளிப்பு (Sour) உப்பு (Salt) வாயுப் பொருட்கள் (Vatha diet) உருளைக் கிழங்கு (Potato) வாழைக் காய் (Plantain) புகையிலை (Tobacco) மது அருந்துதல் (Alcohol) பெண்போகம் (இச்சா பத்தியம்) [Sexual intercourse]

மருத்துவ அறிவுரை:

ஈரமில்லாத் தரையிலும், படுக்கையிலும் படுத்தல் வேண்டும்,
குளிர் காற்று படும்படியான இடத்தில் இருப்பதைத் தவிர்க்கவும்.
உடல் அதிக எடை இருப்பின் எடையைக் குறைக்க வேண்டும்.
அதிக தூரம் நடத்தல், அதிக நேரம் நிற்றல் தவிர்க்கவும்

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